User Manual

EDAN

SE-1010

PC ECG

Release 1.7 with Software Revision 202

CE 0123

About this Manual

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Statement

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The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

Upon request, EDAN may provide, with compensation, necessary circuit diagrams, and other information to help qualified technician to maintain and repair some parts, which EDAN may define as user serviceable.

Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.

WARNING

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

CAUTION

A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

NOTE: A NOTE provides useful information regarding a function or a procedure.

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Chapter 1 Safety Guidance

This chapter provides important safety information related to the use of SE-1010 PC ECG.

1.1 Intended Use

SE-1010 PC ECG is a PC-based diagnostic tool intended to acquire, process and store ECG signals from adult and pediatric patients undergoing stress exercise test or resting test. SE-1010 PC ECG is intended to be used only in hospitals and healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by SE-1010 PC ECG can help users to analyze and diagnose heart disease. However the ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only.

1.2 Warnings and Cautions

To use the system safely and effectively, firstly be familiar with the operation method of Windows and read the user manual in detail to be familiar with the proper operation method for the purpose of avoiding the possibility of system failure. The following warnings and cautions must be paid more attention to during the operation of the system.

Notes:

1. This system is not intended for home use.
2. The pictures and interfaces in this manual are for reference only.

1.2.1 General Warnings

WARNING

1. The system is intended to be used by qualified physicians or personnel professionally trained. They should be familiar with the contents of this user manual before operation.
2. Only qualified service engineers can install this equipment, and only service engineers authorized by the manufacturer can open the shell.
3. The results given by the system should be examined based on the overall clinical condition of the patient, and it can not substitute for regular checking.
4. This system is not intended for treatment.
5. This system is not designed for direct cardiac application.

WARNING

6. **EXPLOSION HAZARD** - Do not use the system in the presence of flammable anesthetic mixtures with oxygen or other flammable agents.
7. **SHOCK HAZARD** - The power receptacle must be a hospital grade grounded outlet. Never try to adapt the three-prong plug to fit a two-slot outlet.
8. Do not use this system in the presence of high static electricity or high voltage equipment which may generate sparks.
9. In order to avoid being burnt, please keep the electrodes far away from the radio knife while using electrosurgical equipment.
10. Only the patient cable supplied by the manufacturer can be used. Or else, the performance and electric shock protection can not be guaranteed.
11. Turn off the system power and remove the power cable before servicing or maintaining the system.
12. Please do not operate the system during servicing or before it is running normally.
13. Make sure that all electrodes are connected to the patient correctly before operation.
14. Ensure that the conductive parts of electrodes and associated connectors, including neutral electrodes, do not come in contact with earth or any other conducting objects.
15. Electrodes with defibrillator protection should be used while defibrillating.
16. The disposable electrodes can only be used for one time.
17. Electrodes of dissimilar metals should not be used; otherwise it may cause a high polarization voltage.
18. Do not touch the patient, bed, table or the system simultaneously while using the system together with a defibrillator.
19. If reusable electrodes with electrode gel are used during defibrillation, the ECG recovery will take more than 10 seconds. The manufacturer recommends the use of disposable electrodes at all times.
20. Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configuration shall comply with the valid version of the standard IEC/EN 60601-1-1. Therefore anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult our technical service department or your local distributor.

WARNING

21. The summation of leakage current should never exceed leakage current limits while several other units are used at the same time.
22. The equipment is protected against malfunctions caused by electrosurgery according to the clause 36.202.101 in the standard IEC60601-2-25.
23. To the patient with a pacemaker, the results given by the system may be invalid.

1.2.2 General Cautions

CAUTION

1. Federal (US) law restricts this device to sale by or on the order of a physician.
2. Avoid liquid splash and excessive temperature. The temperature must be kept between 5 ºC and 40 ºC during operation.
3. Do not use the system in a dusty environment with bad ventilation or in the presence of corrosive.
4. Make sure that there is no intense electromagnetic interference source around the system, such as radio transmitters, mobile phones etc. Attention: large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment is likely to bring electromagnetic interference.
5. Before use, the system, the patient cable, electrodes etc, should be checked. Replacement should be taken if there is any evident defectiveness or aging symptom which may impair the safety or the performance.
6. The following safety checks should be performed at least every 24 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

   a) Inspect the equipment and accessories for mechanical and functional damage.

   b) Inspect the safety related labels for legibility.

   c) Inspect the fuse to verify compliance with the rated current and circuit-breaking characteristics.

   d) Verify that the device functions properly as described in the instructions for use.

   e) Test the protection earth resistance according to IEC/EN 60601-1: Limit: 0.1 ohm.

   f) Test the earth leakage current according to IEC/EN 60601-1: Limit: NC 500 μA, SFC 1000 μA.

CAUTION

g) Test the enclosure leakage current according to IEC/EN 60601-1: Limit: NC 100 μA, SFC 500 μA.

h) Test the patient leakage current according to IEC/EN 60601-1: Limit: NC a.c. 10 μA, d.c. 10 μA; SFC a.c. 50 μA, d.c. 50 μA.

i) Test the patient auxiliary current according to IEC/EN 60601-1: Limit: NC a.c. 10 μA, d.c. 10 μA; SFC a.c. 50 μA, d.c. 50 μA.

j) Test the patient leakage current under single fault condition with mains voltage on the applied part according to IEC/EN 60601-1: Limit: 50 μA (CF).

The data should be recorded in an equipment log. If the equipment is not functioning properly or fails any of the above tests, the equipment has to be repaired.

7. The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal.
8. Precautionary maintenance of this system, including periodically cleaning and checking the appearance, can be finished by users because this maintenance does not touch the interior.
9. Before cleaning or maintaining the system, turn off the system power and remove the power cable.
10. Prevent the detergent from seeping into the equipment while cleaning.
11. Avoid pouring liquid on the equipment while cleaning, and do not immerse any parts of the equipment into any liquid.
12. Do not clean the unit and accessories with abrasive fabric and avoid scratching the electrodes. Removing all dust from the exterior surface of the equipment with a soft brush or cloth, or with a soft cloth which is slightly dampened with a mild detergent solution or cool disinfector. Especially the tie-in and the panel edge should be noticed.
13. Any remainder of detergent should be removed from the unit and the patient cable after cleaning.
14. Do not use chloric disinfectant such as chloride, sodium hypochlorite etc.

1.2.3 Preparation and Operation Warnings (for Exercise ECG)

WARNING

1. Ensure that the main unit and the treadmill are effectively grounded.
2. Test the emergency stop switch of the treadmill before using the system.
3. During the exercise testing, ensure that there are at least 2 experienced physicians present. One of them observes the patient and deals with the emergency.
4. Make sure that there is necessary valid first-aid equipment such as the defibrillator, the blood-pressure meter etc, and necessary valid medication in the exercise testing room.
5. Turn off the system power and disconnect the power cord from the wall outlet after using the system.
6. Press down the emergency stop switch of the treadmill before defibrillating to avoid the hazard to the patient and the operator.
7. Keep the four feet of the treadmill on a horizontal place and make sure it's stably working.
8. Make sure that the power cable of the treadmill is grounded. Don't use other electrical equipment with the same power supply line.
9. Keep the power cable far away from the running treadmill area and the heat surface.
10. Examine the treadmill carefully before using it.
11. Do not do an exercise test if the treadmill is wet.
12. Do not use the treadmill in the open air.
13. The patient undergoing stress exercise testing should wear suitable clothes and shoes.
14. During the stress exercise testing, the patient should not get on or off the treadmill.
15. Remind patients to take care not to fall down from the treadmill.
16. Keep hands, hair, jewelry and loose clothing away from moving parts of the treadmill.
17. After the exercise phase, slow the speed of the treadmill to the minimum, and then stop the treadmill.
18. Children are prohibited from approaching the treadmill alone.
19. Don't insert anything into the treadmill, or place anything on its surface.
20. Press down the emergency stop switch to stop the treadmill immediately the emergency happens.

1.2.4 Contraindications (for Exercise ECG)

Absolute Contraindications:

1. Acute MI (within 2 days)
2. High-risk unstable angina
3. Hemodynamic compromise caused by uncontrolled cardiac arrhythmia
4. Active endocarditis
5. Symptomatic severe aortic stenosis
6. Decompensated symptomatic heart failure
7. Acute pulmonary embolus or pulmonary infarction
8. Acute noncardiac disorder that may affect exercise performance or be aggravated by exercise (eg, infection, renal failure, thyrotoxicosis)
9. Acute myocarditis or pericarditis
10. Physical disability that would preclude safe and adequate test performance
11. The patient opposes the test.

Relative Contraindications:

1. Left main coronary stenosis or its equivalent
2. Moderate stenotic valvular heart disease
3. Electrolyte abnormalities
4. Tachyarrhythmias or bradyarrhythmias
5. Atrial fibrillation with uncontrolled ventricular rate
6. Hypertrophic cardiomyopathy
7. Patients can not cooperate because of mental impairment
8. High-degree AV block

1.3 List of Symbols

	Equipment or part of CF type with defibrillator proof
	Caution
	Consult Instructions for Use
	Recycle
P/N	Part Number
SN	Serial Number
	Date of Manufacture
	Manufacturer
EC REP	Authorized Representative in the European Community
CE 0123	The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.
	It indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.
Rx only (U.S.)	Federal (US) law restricts this device to sale by or on the order of a physician

Chapter 2 Introduction

SE-1010 PC ECG has similar functions with an ordinary electrocardiograph. ECG data can be sampled, analyzed and stored in a PC, and it can be saved in PDF, Word, BMP or JPG format. ECG waves can be frozen and reviewed. Auto measurement and diagnosis are available, and the diagnosis template can be edited.

When a patient with coronary heart disease runs, the added heart load will cause myocardium hypotension, and then the ECG will change abnormally. Therefore, with the function of exercise ECG, SE-1010 PC ECG can also be used to diagnose concealed coronary heart disease and atypical angina pectoris, prescribe the workload for patients with myocardial infarction before they leave hospital, and assess the effect of the treatment.

Note: The exercise ECG function is optional. It is available only if you purchased this function.

With SE-1010 PC ECG, doctors' workload can be reduced greatly.

WARNING

1. This system is intended for use on adult and pediatric patients only.

2. Ensure that there is no other database software in the PC in which our software will be installed.

Note: This system is not designed for direct cardiac application.

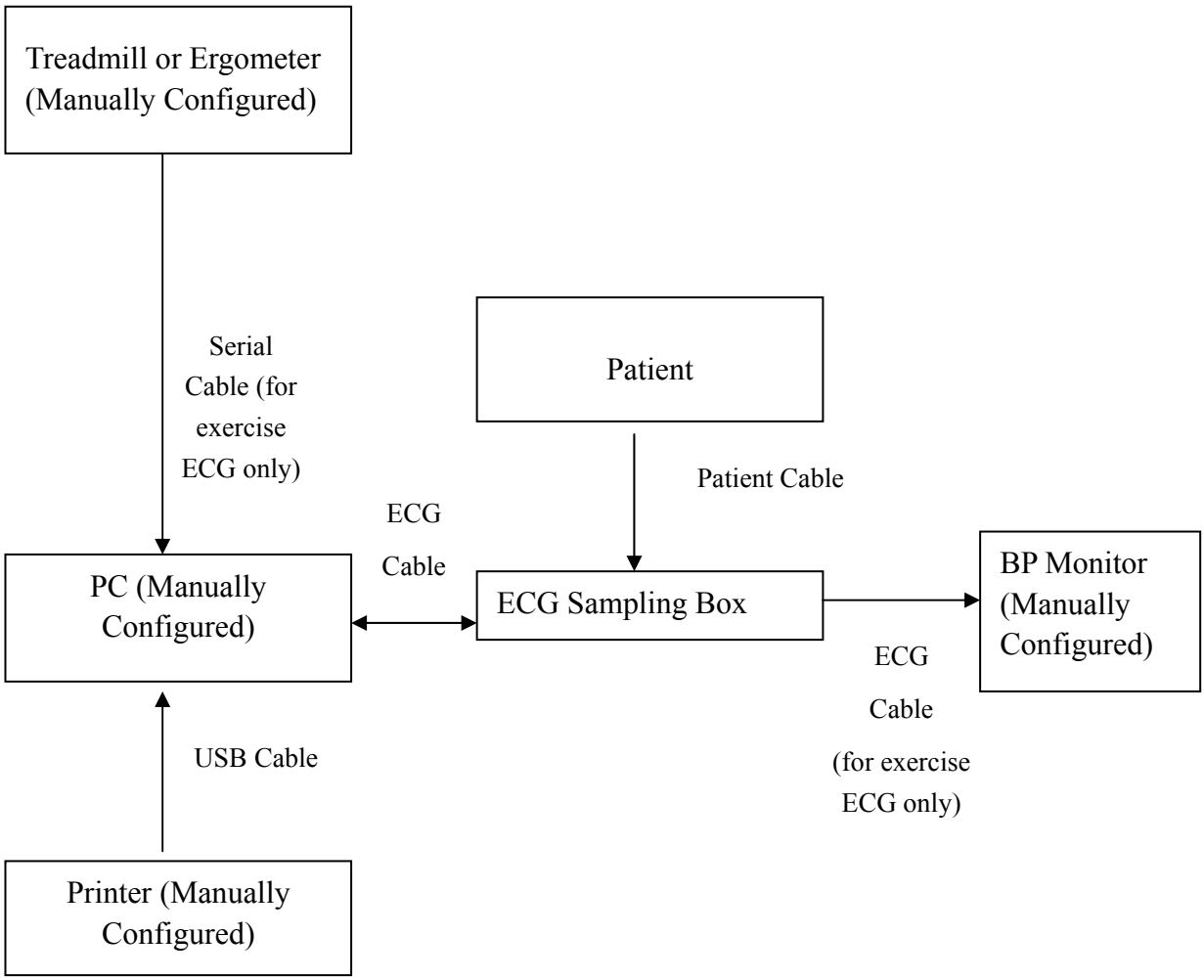
2.1 SE-1010 PC ECG System

SE-1010 PC ECG system includes the following equipment:

- PC in which PC ECG software is installed (Manually Configured)
- ECG Sampling Box
- Printer (Manually Configured)
- Treadmill or Ergometer (Manually Configured)
- Patient Cable
- Electrodes
- Softdog

Note: If the PC is not purchased from our company, we will not be held responsible for the maintenance of the PC hardware or the operating system.

SE-1010 PC ECG System

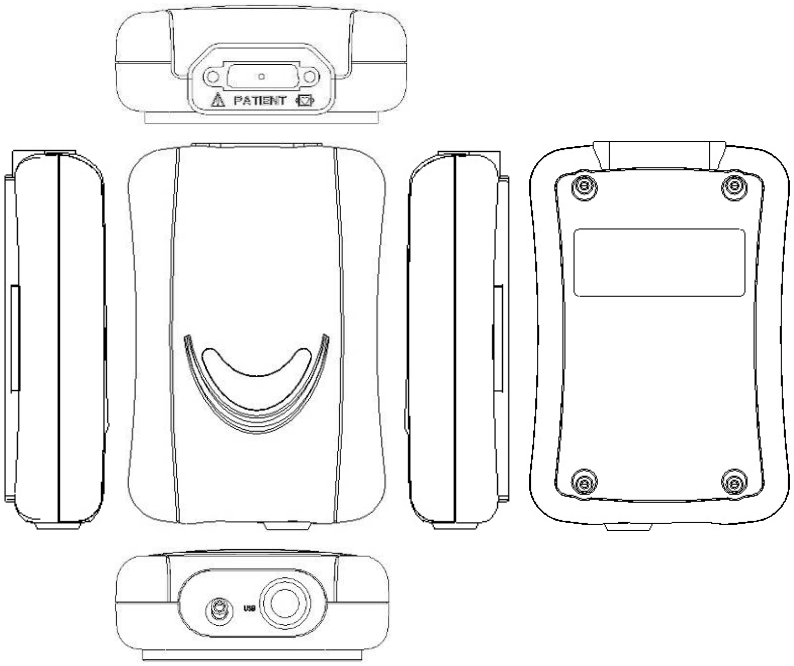


WARNING

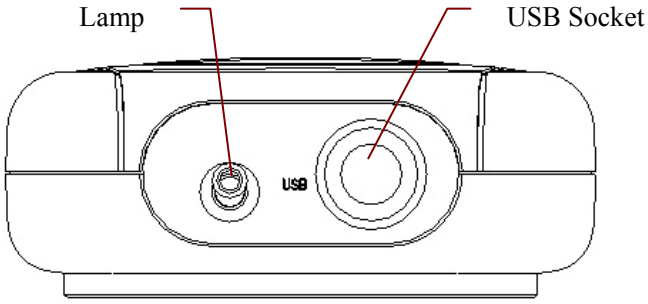
The system should be installed by a qualified service engineer. Do not power on the system until all cables are properly connected and verified.

2.2 ECG Sampling Box Appearance

ECG Sampling Box Appearance

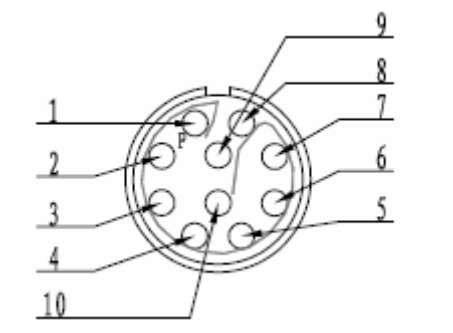


Front Panel



Name	Explanation
Lamp	When the ECG sampling box is powered by the PC, the lamp will be lit.
USB Socket	Connecting to the USB socket of the PC with a USB cable

USB Socket



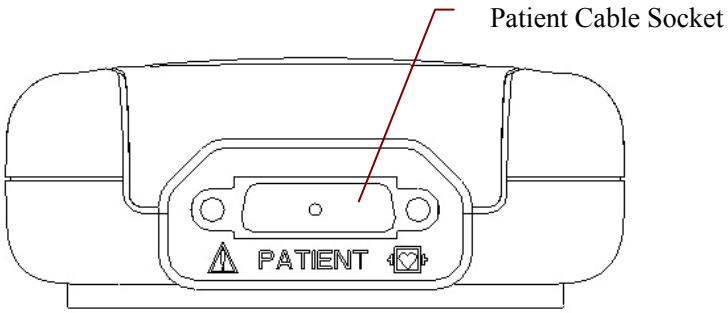
Definitions of corresponding pins:

Pin	Signal	Pin	Signal
1	GND	**6**	GND
2	VCC	**7**	GND
3	QRS	**8**	GND
4	GND	**9**	D-
5	GND	**10**	D+

WARNING

1. When the computer connected to the USB cable is powered on, do not connect the USB cable to the ECG sampling box; when the system is powered on, do not disconnect the USB cable from the ECG sampling box.
2. It is not necessary or recommended to regularly disconnect the USB cable from the ECG sampling box. Disconnect the USB cable from the PC if necessary.

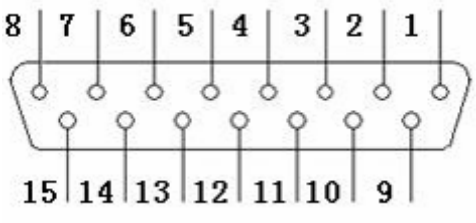
Back Panel



: Applied part of type CF with defibrillator proof

⚠: Caution

Patient Cable Socket

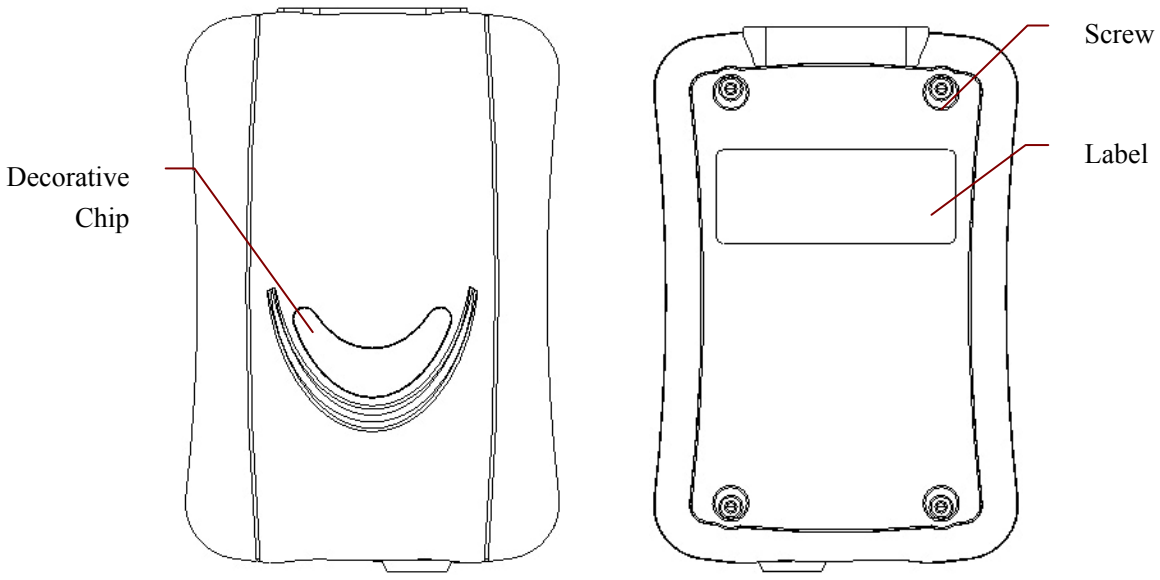


Definitions of corresponding pins:

Pin	Signal	Pin	Signal	Pin	Signal
1	C2 / V2	**6**	SH	**11**	F / LL
2	C3 / V3	**7**	NC	**12**	C1 / V1 or NC
3	C4 / V4	**8**	NC	**13**	C1 / V1
4	C5 / V5	**9**	R / RA	**14**	RF (N) /RL or NC
5	C6 / V6	**10**	L / LA	**15**	RF (N) / RL

Note: The left side of "/" is European standard, and the right side is American standard.

Top Panel and Bottom Panel



WARNING

1. Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configuration shall comply with the valid version of the standard IEC/EN 60601-1-1. Therefore anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult our technical service department or your local distributor.
2. The summation of leakage current should never exceed the leakage current limit while several other units are used at the same time.

2.3 Features

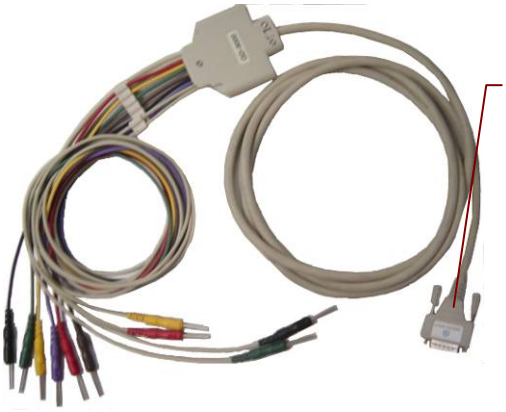
- Powerful functions, friendly interfaces and easy operation
- 3/6/12-channel ECG waves are displayed and printed simultaneously
- ECG waves can be frozen and reviewed
- Supporting auto measurement and diagnosis
- Measurement point adjustment and re-analysis, manual measurement with an electronic ruler of high precision
- Perfect data management and processing functions
- Reports can be printed in PDF, Word, JPG or BMP format
- Supporting multi-language
- Updated to be a network electrocardiograph, transmitting ECG data over LAN or WAN or INTERNET
- Automatic baseline adjustment for optimal printing
- High performance filters guarantee stable ECG waveforms
- Real-time analysis, real-time displaying and printing 12-lead simultaneous ECG waveforms
- Nine analysis functions including Normal ECG, Frequency ECG, High Frequency ECG,

QT Dispersion, Vector ECG, Time Vector ECG, HRT analysis, HRV analysis and Signal Averaged ECG (Only for resting ECG)

The following features are only for the exercise test function of SE-1010 PC ECG

- Automatically controlling and adjusting the speed and the elevation of the treadmill
- Supporting many kinds of treadmills and ergometers
- Providing classical exercise protocols; new exercise protocols can be added to the system
- ST segment analysis and measurement of 12-lead waveforms while sampling ECG; ST position is adjustable while sampling ECG
- Providing summaries, ST analysis, wave reviews and trends
- Providing specific statistic data of each lead in each stage
- Providing average waves of each lead in each stage for you to observe the changes of ST segments among different stages

Chapter 3 Assembling SE-1010 PC ECG System



Patient Cable for Resting ECG

Patient Cable for Exercise ECG

ECG Sampling Box

Cable for Exercise ECG

Cable for Resting ECG

For resting ECG,

1. Insert plug 1 of the patient cable into socket 3 of the ECG sampling box.

2. Insert plug 8 of the cable into socket 4 of the ECG sampling box.

3. Insert plug 9 of the cable into the USB socket of the PC.

4. Connect a printer to the PC.

5. Insert the LPT softdog into the parallel interface of the PC, or insert the USB softdog into the USB socket of the PC.

6. Make sure that the above parts are properly connected, and then connect the PC, and the printer to the power supply.

For exercise ECG,

1. Insert plug 2 of the patient cable into socket 3 of the ECG sampling box.

2. Insert plug 5 of the cable into socket 4 of the ECG sampling box.

3. Insert plug 6 of the cable into the USB socket of the PC.

4. Connect plug 7 of the cable to the BP monitor.

WARNING

Only stress BP monitors can be used.

5. Connect a treadmill or an ergometer to the PC.

6. Connect a printer to the PC.

7. Insert the LPT softdog into the parallel interface of the PC, or insert the USB softdog into the USB socket of the PC.

8. Make sure that the above parts are properly connected, and then connect the PC, treadmill/ergometer and printer to the power supply.

WARNING

1. Use a special grounded socket to get accurate voltage and current.

2. When using a notebook computer with a two-prong plug, please connect a grounded printer to avoid power interference.

Chapter 4 Installing SE-1010 PC ECG Software

4.1 System Running Environment

4.1.1 Requirements on the Hardware of the PC

CPU:	Pentium P4, Celeron D 310 or above
System Memory (RAM):	512MB or above
Main Board	Recommend the main board of Intel chipset
Hard Disk:	40G or above
Printer:	ink jet printer of more than 600dpi or laser printer Recommend HP2035, HP5568, CANON3500, CANON1800
Display:	17" TFT (1024×768 resolution) or 19" TFT (1440×900 resolution), 16 bit actual color, regular icon and font setup
Others:	CD-ROM (24 × or above)

4.1.2 Requirements on the Software of the PC

- Windows XP PROFESSIONAL SP2/SP3, Windows Vista (32/64 bit) or Windows 7 (32/64 bit)
- MSDE2000 (Microsoft SQL Server 2000 Desktop Engine) or Microsoft SQL Server 2005 Express

CAUTION

1. Ensure that there is no other database software in the PC in which our software will be installed.

2. Ensure that there is a graphic driver installed in the PC. Otherwise, the displayed ECG waves may be abnormal.

4.2 About Installation Interface

Insert the installation CD into CD-ROM, and double-click on **Setup.exe**

on the installation CD to open the following installation interface.

Figure 4-1 Installation Interface

Click on the **Install** button to install PC ECG. Click on the **Next** button continually during installation.

After installing PC ECG, click on the **Install** button on the installation interface. Then the **Environment Detection** interface pops up. Check the installing status of all the components. If the **Environment Detection** interface shows that a certain component needs to be installed, please install it manually.

Note: During the installation in Windows 7/Vista, only if **Add user to the SQL Server Administrator role** is selected, can the database be available.

Click on the **Help** button to see the installation guide.

For details on installing SE-1010 software, please refer to <<SE-1010 PC ECG Installation Guide>>.

Chapter 5 Preparations Before Operation

5.1 Preparing the Patient

5.1.1 Instructing the Patient

Before attaching the electrodes, greet the patient and explain the procedure. Explaining the procedure decreases the patient's anxiety. Reassure the patient that the procedure is painless. Privacy is important for relaxation. When possible, prepare the patient in a quiet room or area where others can't see the patient. Make sure that the patient is comfortable. The more relaxed the patient is, the less the ECG will be affected by noise.

5.1.2 Preparing the Skin

Thorough skin preparation is very important. The skin is a poor conductor of electricity and frequently creates artifacts that distort the ECG signals. By performing methodical skin preparation, you can greatly reduce the possibility of noise caused by muscle tremor and baseline drift, ensuring high-quality ECG waves. There is natural resistance on the skin surface due to dry, dead epidermal cells, oils and dirt.

To prepare the skin

1 Shave hair from electrode sites, if necessary. Excessive hair prevents a good connection.

2 Wash the area thoroughly with soap and water.

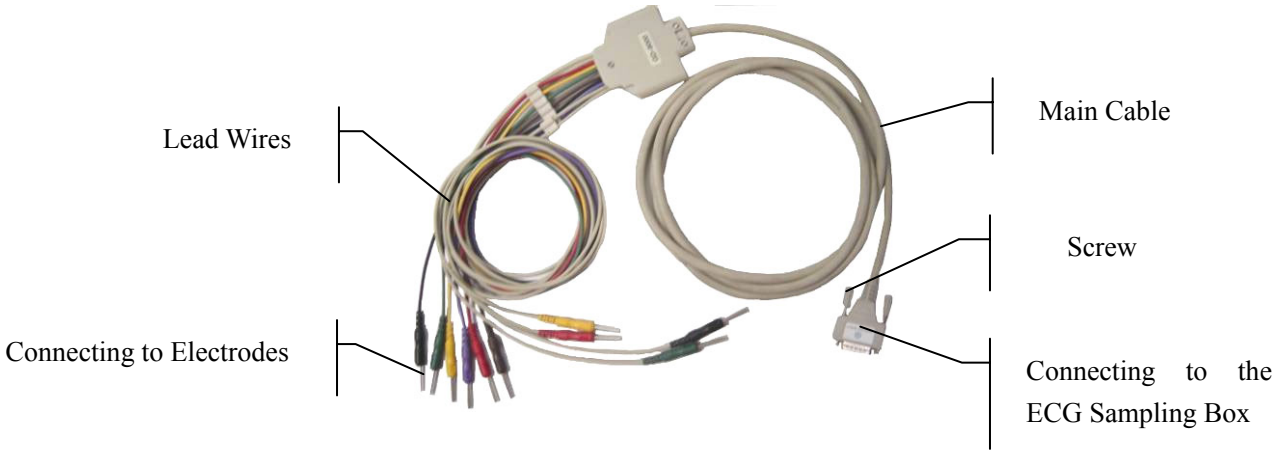
3 Dry the skin with a gauze pad to increase capillary blood flow to the tissues and to remove the dead, dry skin cells and oils.

5.2 Connecting the Patient Cable to the Electrodes

WARNING

The performance and electric shock protection can be guaranteed only if the original patient cable and electrodes of the manufacturer are used.

The patient cable includes main cable and lead wires which can be connected to electrodes according to the colors and identifiers.



Patient Cable for Resting ECG

Patient Cable for Exercise ECG

1. Connect the patient cable to the ECG sampling box. For details, see Chapter 3, “Assembling SE-1010 PC ECG System”.

2. Align all lead wires of the patient cable to avoid twisting, and connect the lead wires to the corresponding electrodes according to the colors and identifiers. Firmly attach them.

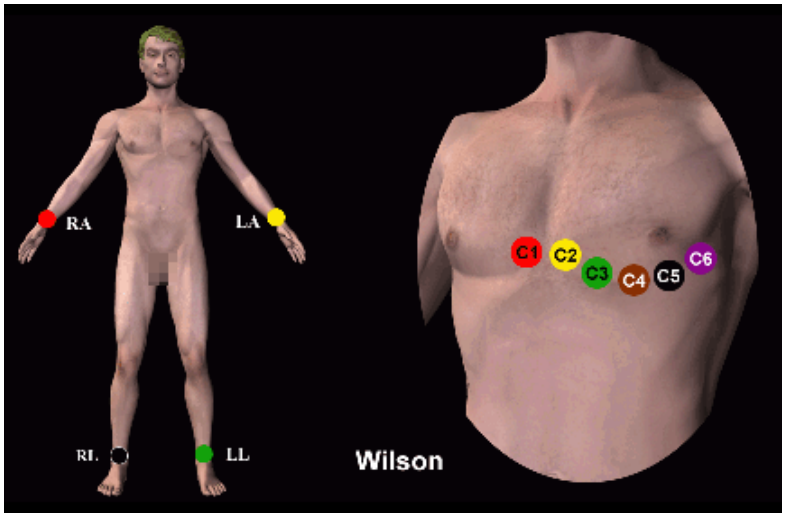
5.3 Attaching Electrodes (for Resting ECG)

The identifiers and color codes of electrodes used comply with IEC/EN requirements. In order to avoid incorrect connections, the electrode identifiers and color codes are specified in Table 5-1. Moreover the equivalent codes according to American requirements are given in Table 5-1 too.

Table 5-1 Electrodes and Their Identifiers and Color Codes

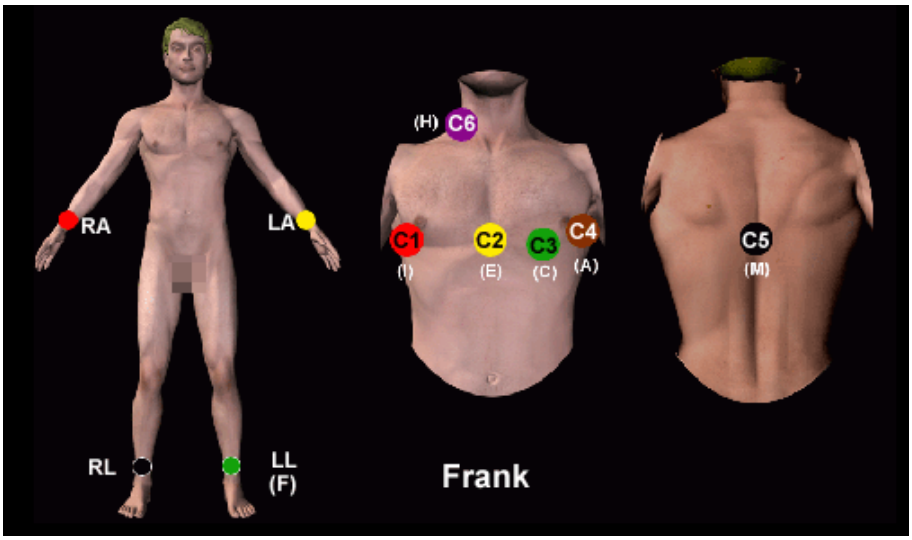
		European		American	
WILSON	**FRANK**	**Identifier**	**Color Code**	**Identifier**	**Color Code**
Right arm	Right arm	R	Red	RA	White
Left arm	Left arm	L	Yellow	LA	Black
Right leg	Right leg	N or RF	Black	RL	Green
Left leg	Left leg	F	Green	LL	Red
Chest 1	I	C1	White/Red	V1	Brown/Red
Chest 2	E	C2	White/Yellow	V2	Brown/Yellow
Chest 3	C	C3	White/Green	V3	Brown/Green
Chest 4	A	C4	White/Brown	V4	Brown/Blue
Chest 5	M	C5	White/Black	V5	Brown/Orange
Chest 6	H	C6	White/Violet	V6	Brown/Violet

5.3.1 Wilson Lead System



C1: Fourth intercostal space at the right border of the sternum
C2: Fourth intercostal space at the left border of the sternum
C3: Fifth rib between C2 and C4
C4: Fifth intercostal space on the left midclavicular line
C5: Left anterior axillary line at the horizontal level of C4
C6: Left midaxillary line at the horizontal level of C4

5.3.2 Frank Lead System



FRANK lead system is usually adopted when PC ECG is used to produce VCG. The conventional letter designations for the electrodes and their respective positions are:

E/C2: at the front midline

M/C5: at the back midline

I/C1: at the right mid-axillary line

A/C4: at the left mid-axillary line

C/C3: at 45º angle between the front midline and the left mid-axillary line

F: on the left leg

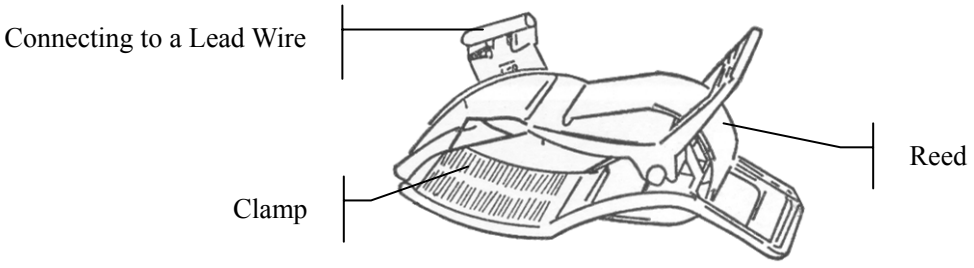
N: on the right leg

H: on the back of the neck

The first five electrodes (E, M, I, A and C) are all located at the same transverse level -- approximately at the interspace between the fourth rib and the fifth rib.

5.3.3 Attaching Electrodes to the Patient

For Limb Electrodes:



1. Clean the electrode area which is in a short distance above the ankle or the wrist with alcohol.

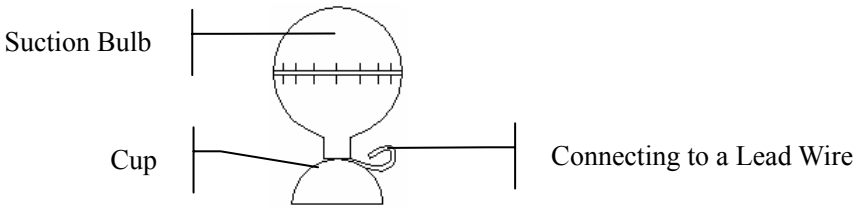
2. Daub the electrode area on the limb with gel evenly.

3. Place a small amount of gel on the metal part of the limb electrode clamp.

4. Connect the electrode to the limb, and make sure that the metal part is placed on the electrode area above the ankle or the wrist.

5. Attach all limb electrodes in the same way.

For Chest Electrodes:



1. Clean the electrode area on the chest surface with alcohol.

2. Daub the round area of 25mm in diameter on each electrode area with gel evenly.

3. Place a small amount of gel on the brim of the chest electrode's metal cup.

4. Place the electrode on the chest electrode area and squeeze the suction bulb. Unclench it and the electrode is adsorbed on the chest.

5. Attach all chest electrodes in the same way.

Chest Electrode (Only for C5 in Frank Lead System):

Snap/Banana Socket Adapter:

Disposable Electrode:

Disposable Electrode Connection:

1) Connect the snap/banana socket adapter to the lead wire.

2) Connect the snap/banana socket adapter to the disposable electrode.

3) Clean the electrode area at the back midline with 75% alcohol.

4) Attach the disposable electrode to the electrode area at the back midline.

The quality of ECG waveform will be affected by the contact resistance between the patient and the electrode. In order to get a high-quality ECG, the skin-electrode resistance must be minimized while connecting electrodes.

WARNING

1. Make sure that all electrodes are connected to the patient correctly before operation.

2. Make sure that the conductive parts of electrodes and associated connectors, including neutral electrodes, do not come in contact with earth or any other conducting objects.

CAUTION

The disposable electrodes can only be used for one time.

5.4 Attaching Electrodes to the Patient (for Exercise ECG)

The identifiers and color codes of electrodes used comply with IEC/EN requirements. In order to avoid incorrect connections, the electrode identifiers and color codes are specified in Table 5-2. Moreover the equivalent codes according to American requirements are given in Table 5-2 too.

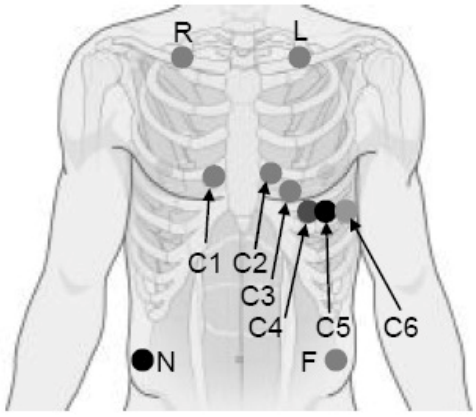
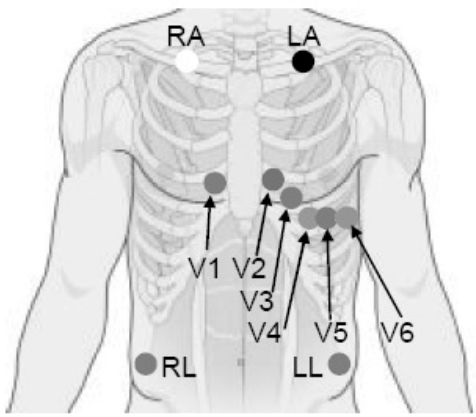
IEC	AHA
	

Table 5-2 Electrodes and their identifiers and color codes

European		American	
Electrodes	**Color code**	**Electrodes**	**Color code**
R	Red	RA	White
L	Yellow	LA	Black
N or RF	Black	RL	Green
F	Green	LL	Red
C1	White/Red	V1	Brown/Red
C2	White/Yellow	V2	Brown/Yellow
C3	White/Green	V3	Brown/Green
C4	White/Brown	V4	Brown/Blue
C5	White/Black	V5	Brown/Orange
C6	White/Violet	V6	Brown/Violet

The Precordial Electrodes' Positions on Body Surface:

C1: Fourth intercostal space at the right border of the sternum

C2: Fourth intercostal space at the left border of the sternum

C3: Fifth rib between C2 and C4

C4: Fifth intercostal space on the left midclavicular line

C5: Left anterior axillary line at the horizontal level of C4

C6: Left midaxillary line at the horizontal level of C4

The Extremity Electrodes' Positions on Body Surface:

R/L: below the right/left clavicle

N/F: below the right/left rib

The quality of ECG waveform will be affected by the contact resistance between the patient and the electrode. In order to get a high-quality ECG, the skin-electrode resistance must be minimized while connecting electrodes.

Electrodes Connection:

1) Align all lead wires of the patient cable to avoid twisting, and connect the disposable

electrodes to the lead wires.

2) Clean the electrode areas on the body surface with 75% alcohol.

3) Attach the disposable electrodes to the electrode sites.

Note: The quality and the placement of the electrode will directly influence the quality of exercise ECG. The wrong placement and use of electrodes will cause incorrect analysis results.

WARNING

1. Make sure that all electrodes are connected to the patient correctly before operation.

2. Make sure that the conductive parts of electrodes and associated connectors, including neutral electrodes, do not come in contact with earth or any other conducting objects.

CAUTION

The disposable electrodes can only be used for one time.

5.5 Inspection Before Test

In order to avoid safety hazards and get good ECG records, the following inspection procedure is recommended before operation.

1) Environment:

- Make sure that there is no electromagnetic interference source around the equipment, especially large medical electrical equipment such as electrosurgical equipment, radiological equipment, magnetic resonance imaging equipment etc. Switch off these devices when necessary.
- Keep the examination room warm to avoid muscle action voltages in ECG signals caused by cold.

2) Power Supply:

- Check whether the power cord is connected well. The grounded outlet should be used.

3) Patient Cable:

- Check whether the patient cable is connected to the ECG sampling box firmly, and keep it far away from the power cord.

4) **Electrodes**:

- Check whether all electrodes are connected to lead wires of the patient cable correctly.
- Ensure that the electrodes do not contact.

5) **Patient**:

- The patient should not come into contact with conducting objects such as earth, metal parts etc.
- Ensure the patient is warm and relaxed, and breathes calmly.

WARNING

1. The system is intended to be used by qualified physicians or personnel professionally trained. They should be familiar with the contents of this user manual before operation.

2. Before connecting the device to the power line, make sure that the voltage and frequency ratings of your power line match those indicated on the device label. For details, see Appendix 1, “Technical Specifications”.

3. Before use, the system, patient cable, electrodes etc. should be checked. Replacement should be taken if there is any evident defectiveness or aging symptom which may impair the safety or the performance.

Chapter 6 Operation Instructions for Resting ECG

Double-click on the shortcut icon

on the desktop.

is the desktop icon for SE-1010 PC ECG.

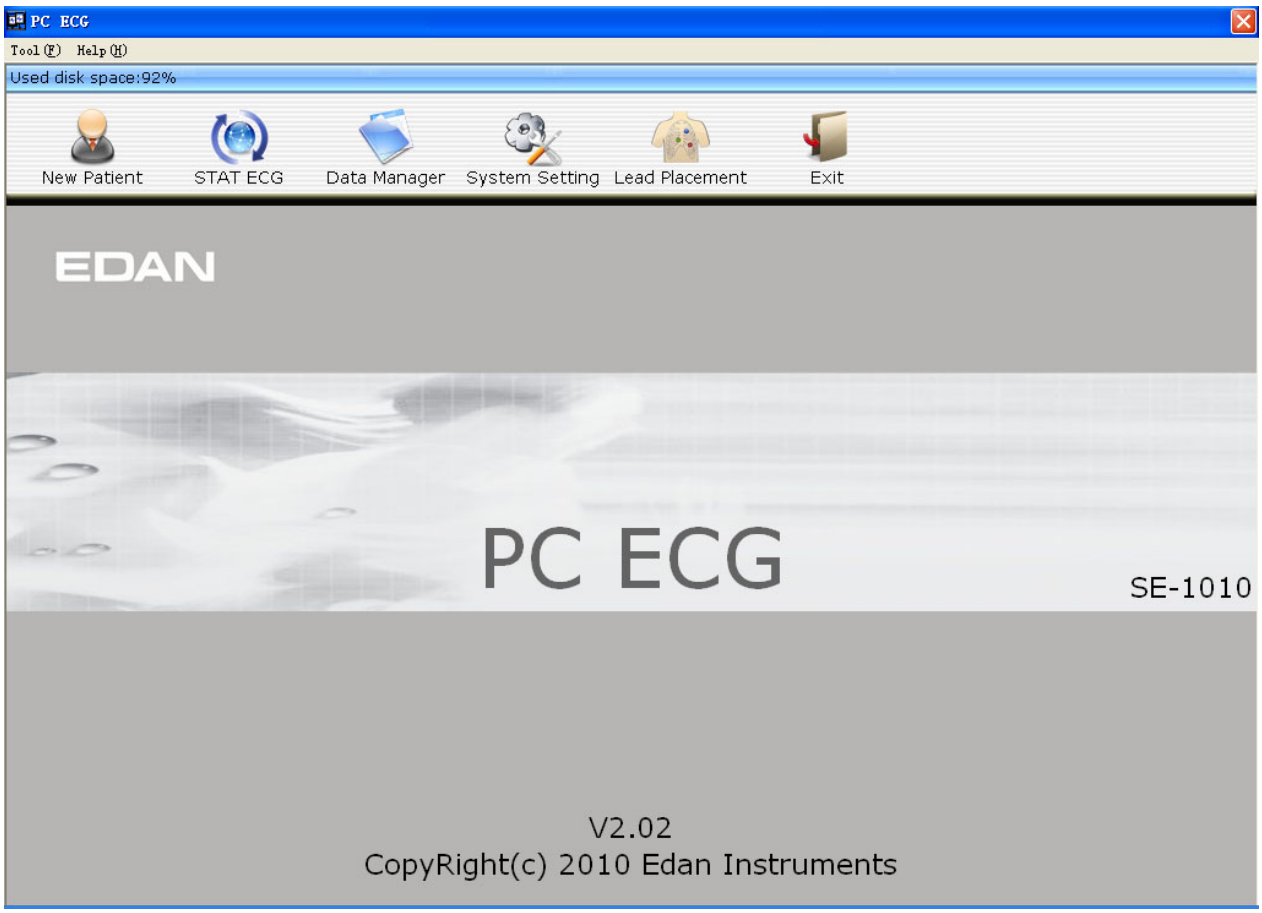


Figure 6-1 Initial Interface

The toolbar contains six buttons. From left to right, they are **New Patient**, **STAT ECG**, **Data Manager**, **System Setting**, **Lead Placement** and **Exit**.

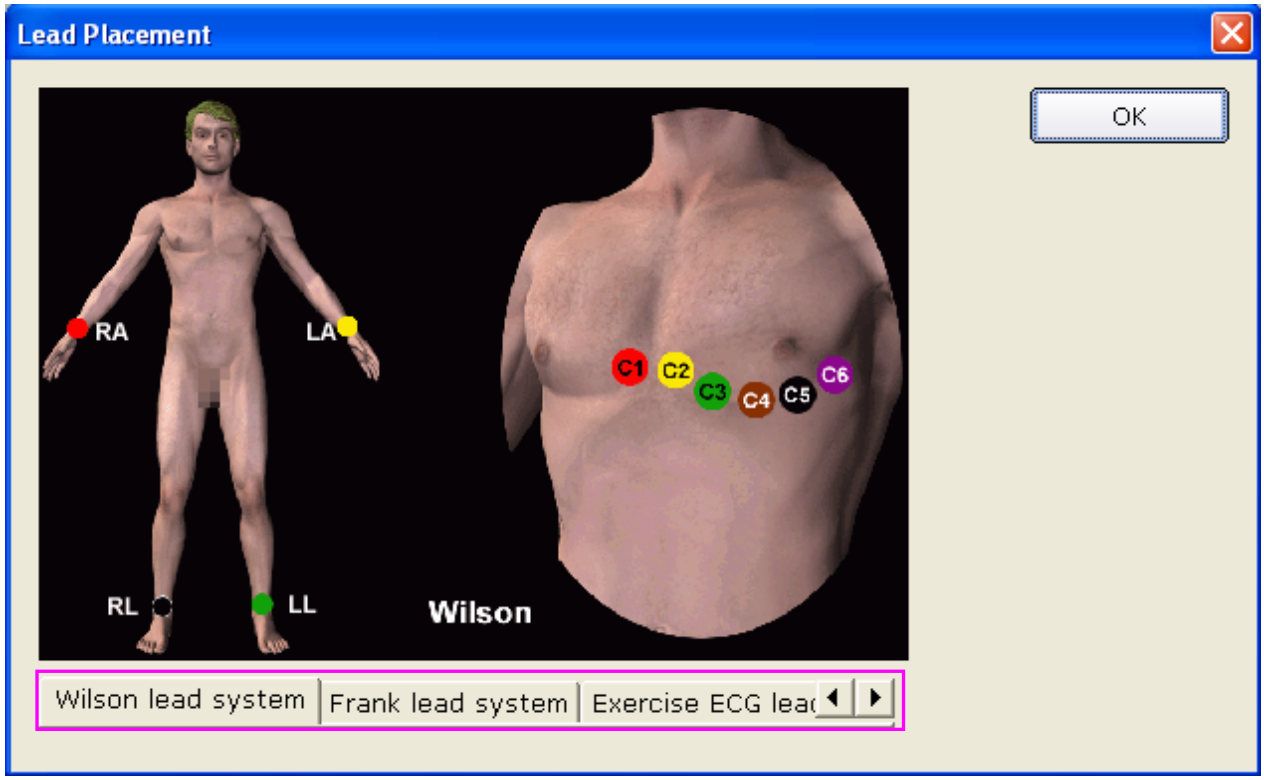
Below the toolbar, the software name, version number and copyright information can be seen.

Click on **Help (H)** to see the help information.

Click on the **Exit** button on the initial interface to exit the system.

6.1 Viewing Lead Placement Information

1. Click on the **Lead Placement** button on the initial interface to display the **Lead Placement** window.



2. Click on **Wilson lead system**, **Frank lead system** or **Exercise ECG lead system** to view the lead placement information in the corresponding system.

6.2 Selecting a Patient Record to Start a New Test

Click on the **Data Manager** button on the initial interface (Figure 6-1) to open the **Data Manager** interface (Figure 6-2).

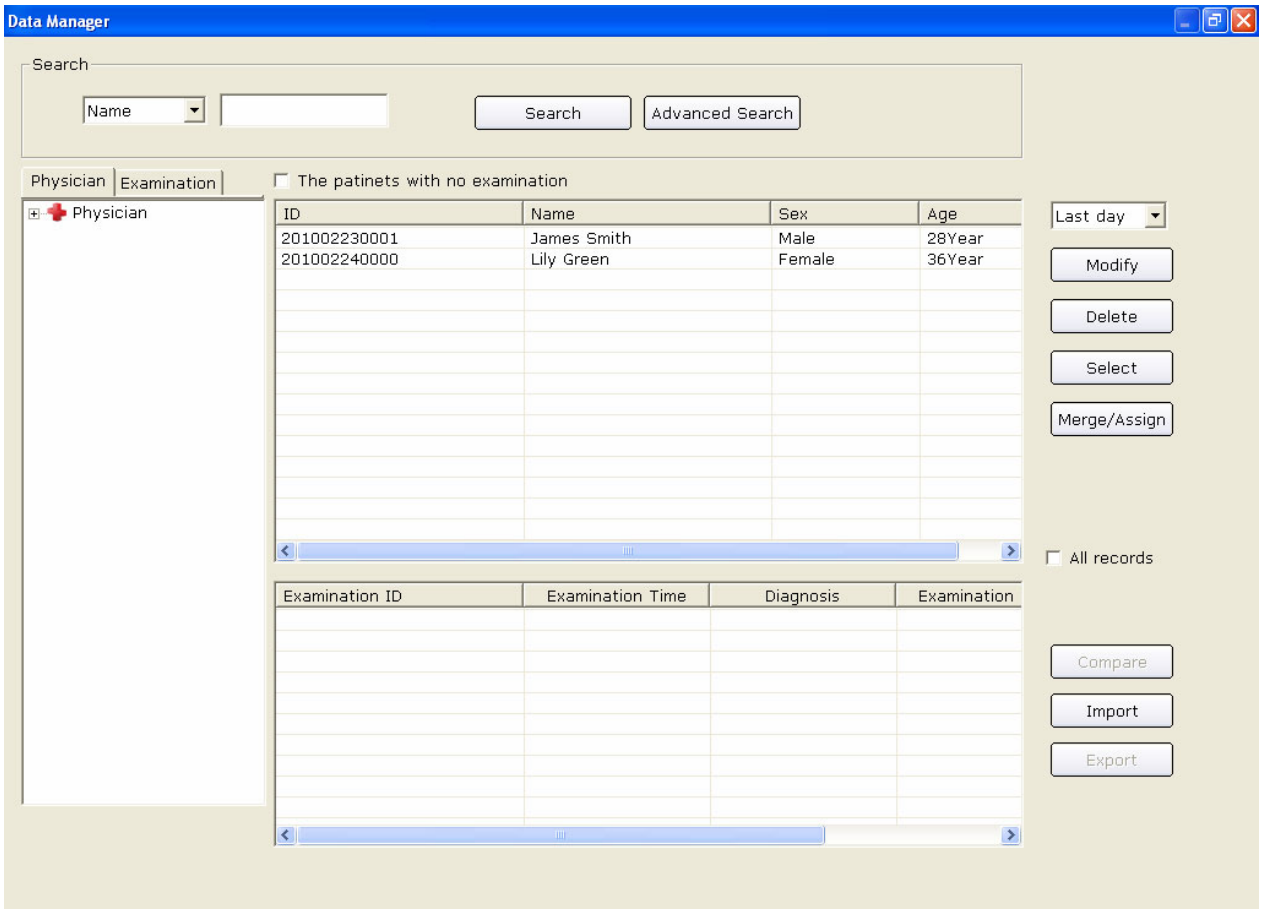
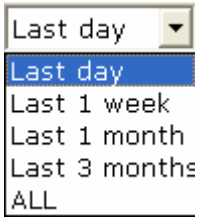
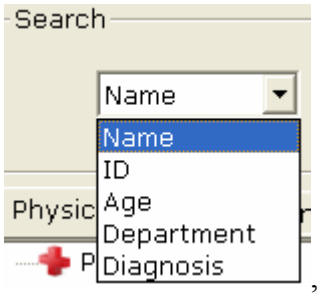


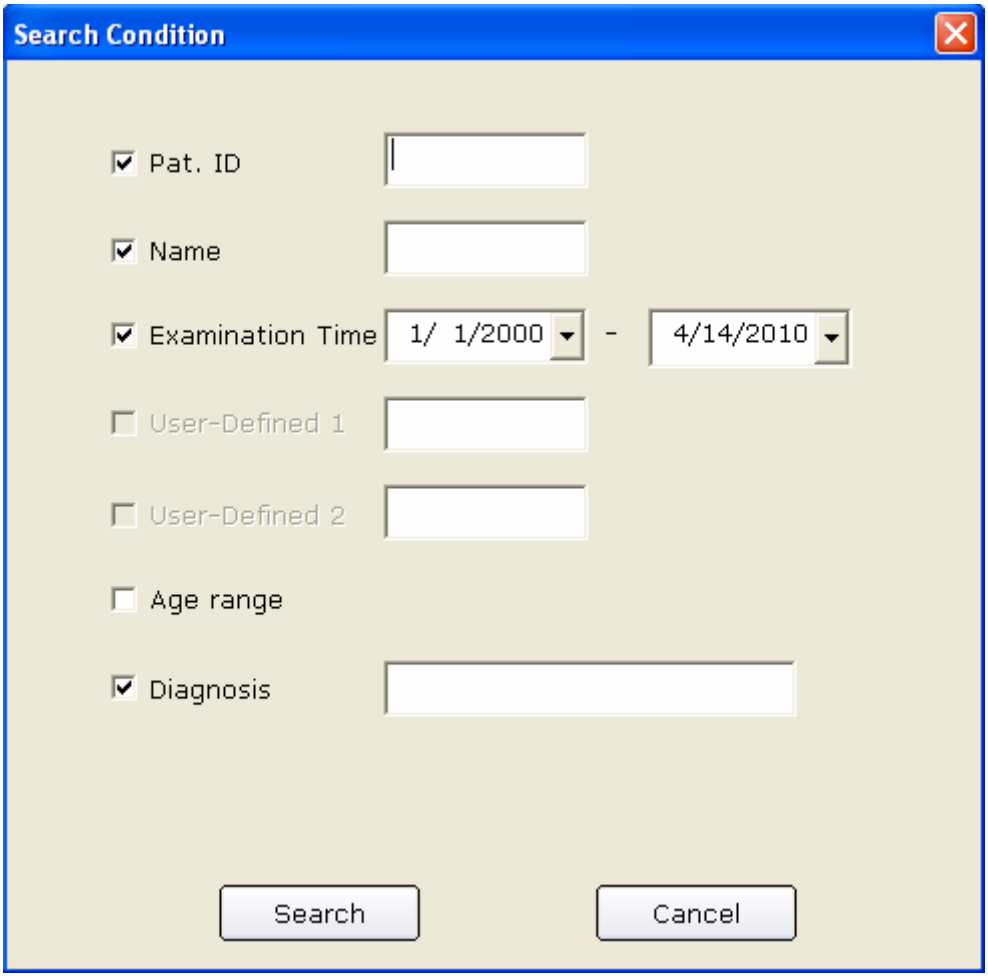
Figure 6-2 Data Manager Interface

1. Select a search item in the pull-down list  on the **Data Manager** interface. Then all the patient records which meet the search condition are listed in the patient information list.

2. Or select a search item in the pull-down list  , enter the corresponding information in the right textbox, and then click on the **Search** button. All the patient records which meet the conditions will be displayed in the patient information list.

3. Or click on **Advanced Search** to display the **Search Condition** window. Enter the search

conditions, and click on the **Search** button, and all the patient records which meet the conditions will be displayed in the patient information list.



4. Click on the patient record in the patient information list and click on the **Select** button to open the **Patient information** interface. Or double-click on the patient record in the patient information list to open the **Patient information** interface.

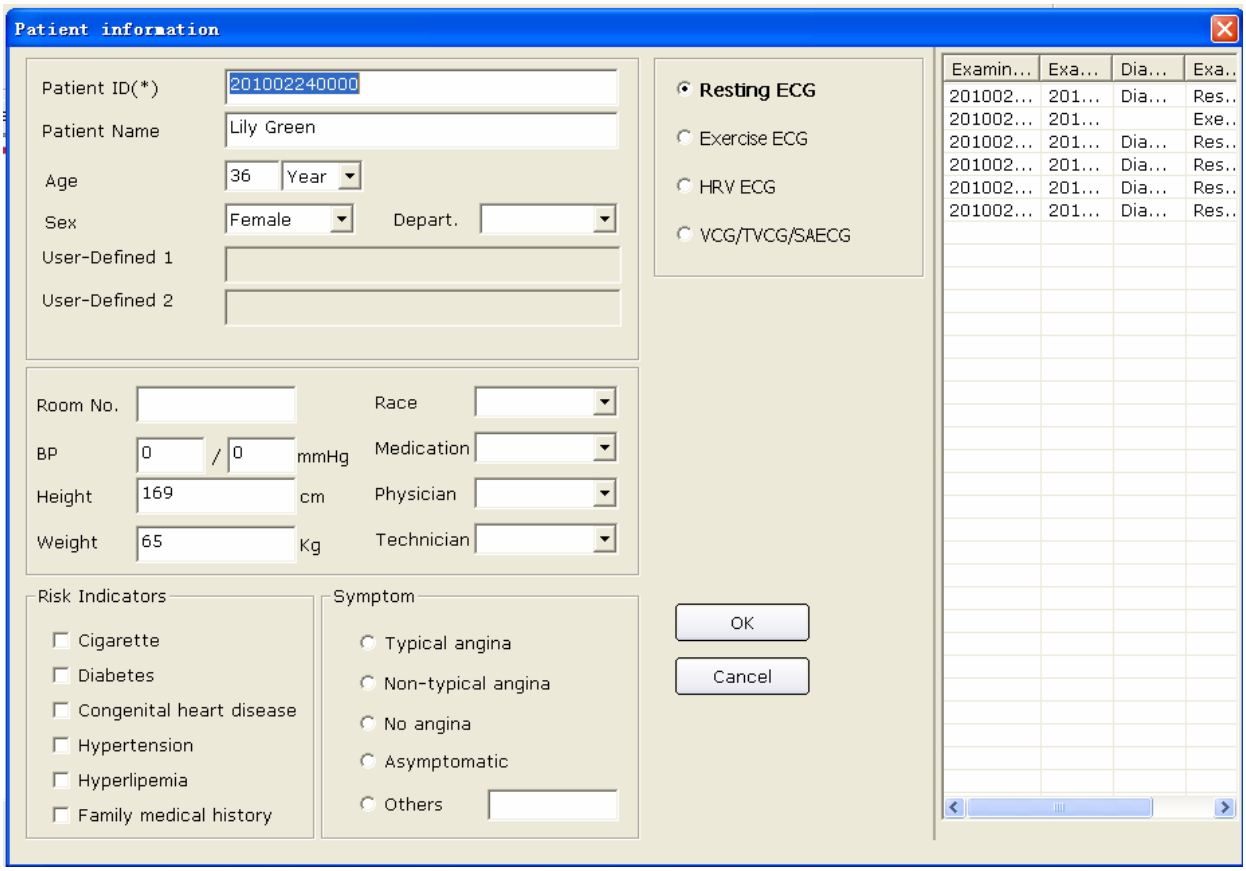
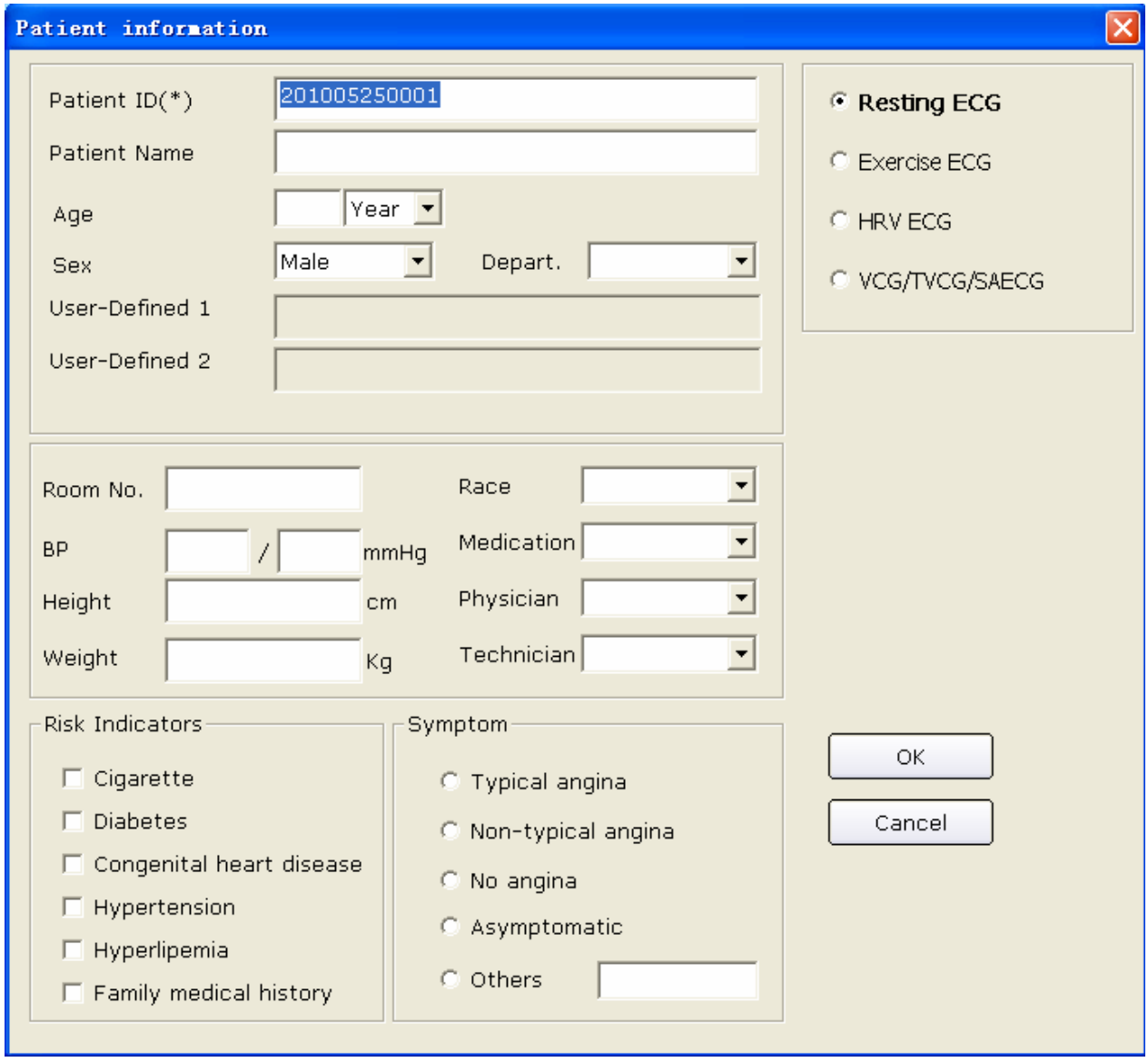


Figure 6-3 Patient Information Interface

6.3 Entering New Patient Information

If the patient is a new one, you can click on the **New Patient** button

on the initial interface (Figure 6-1) to display the **Patient information** interface.



Then you need to input the patient's related information.

1. Input basic information, such as patient ID, name, sex, age, etc.

User-defined 1 and User-defined 2: You can input other related information such as patients' medical records.

User-defined 1 and User-defined 2 can be set on the basic information setup interface (Figure 9-1). Before setting them, the two items on the **Patient information** interface are unavailable. For details, please refer to Section 9.1.1, "Setting Basic Information".

Note: On the **Patient information** interface, patient ID is a must. You can use the number generated by the system or input a number manually. Patient ID can be a random character string excluding '/', '\', ':', '*', '?', '<', '>' and '|'.

2. Input additional information, such as BP, height, weight, medication and race.

3. Select risk indicators and symptoms.

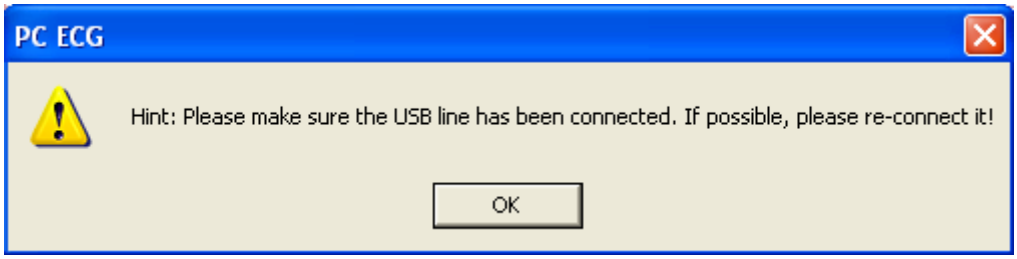
6.4 Selecting Sampling Type

You can select a sampling type on the **Patient information** interface.

6.5 Sampling Resting ECG

After inputting the patient information, click on the **OK** button on the **Patient information** interface to open the ECG sampling interface.

Before sampling, if you do not connect the PC to the ECG sampling box, the following hint will pop up.



The system begins to pre-sample ECG.

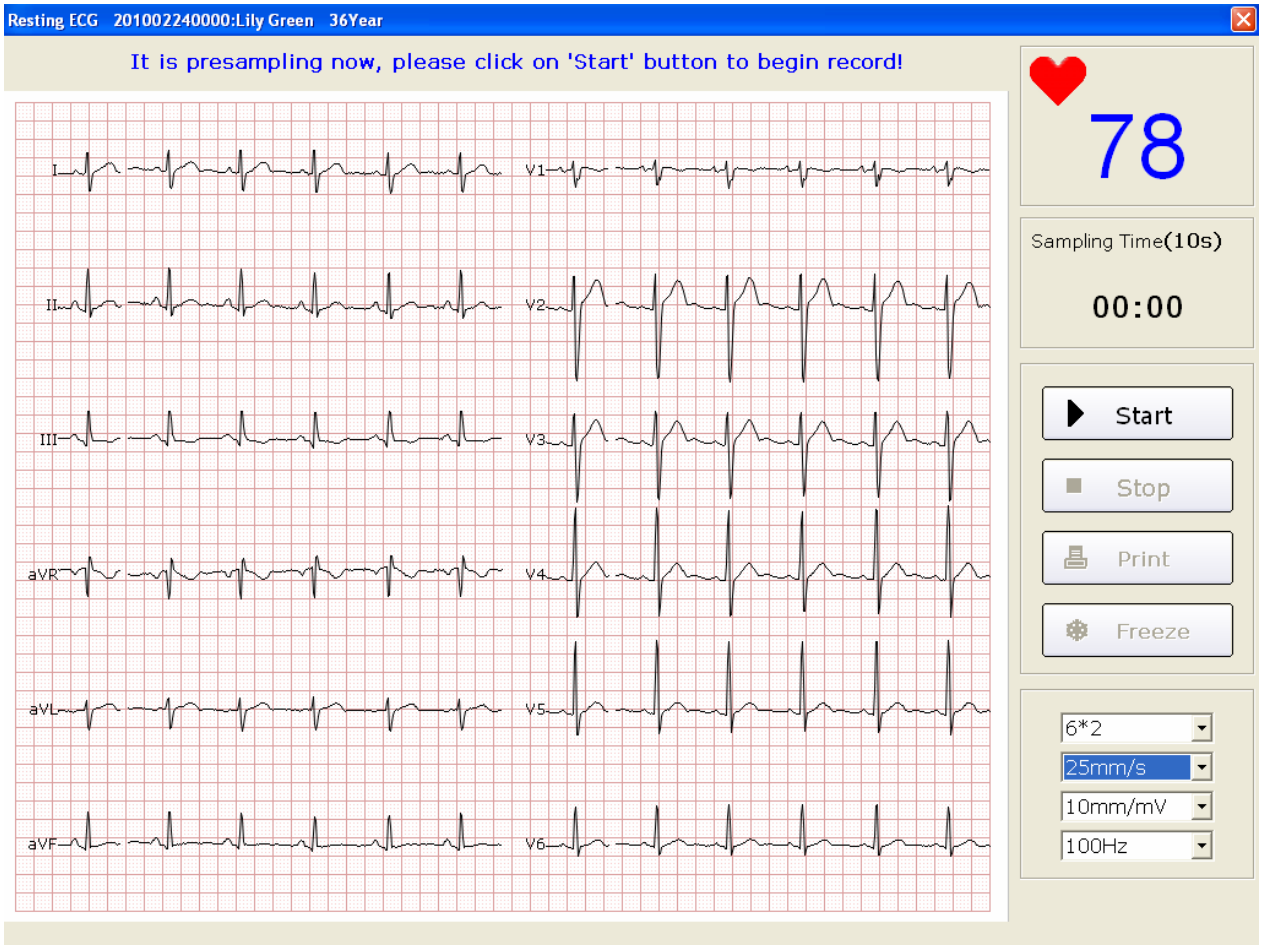
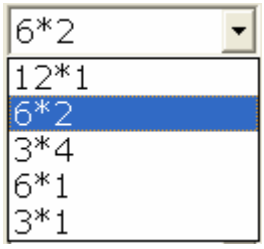


Figure 6-4 Pre-Sampling Interface

6.5.1 Specifying Display Mode



There are five display modes including **12*1**, **6*2**, **3*4**, **6*1**, and **3*1**.

When the display mode is set to **12*1**, 12-channel ECG waves are displayed on one screen simultaneously.

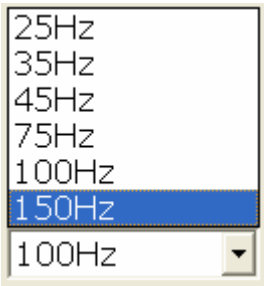
When the display mode is set to **6*2**, 12-channel ECG waves are displayed in 2 groups of 6 on one screen.

When the display mode is set to **3*4**, 12-channel ECG waves are displayed in 4 groups of 3 on one screen.

When the display mode is set to **6*1**, 6-channel ECG waves are displayed on one screen.

When the display mode is set to **3*1**, 3-channel ECG waves are displayed on one screen simultaneously.

6.5.2 Specifying Lowpass Filter



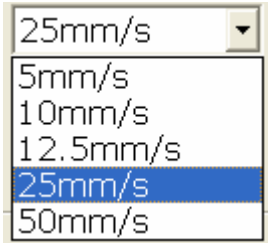
Lowpass Filter restricts the bandwidth of input signals. The cutoff frequency can be set to **25Hz**, **35Hz**, **45Hz**, **75Hz**, **100Hz**, or **150Hz**. The input signals whose frequency is higher than the set cutoff frequency will be attenuated.

6.5.3 Specifying Gain

You can set the indicated length of 1mV ECG on the paper.

You can set the gain to **2.5mm/mV**, **5mm/mV**, **10mm/mV** or **20mm/mV**.

6.5.4 Specifying Speed



You can set the paper speed to **5mm/s**, **10mm/s**, **12.5mm/s**, **25mm/s** or **50mm/s**.

6.5.5 Recording ECG Data

When the pre-sample ECG waves are steady, you can click on the **Start** button to save the sampled ECG data to the designated directory. Please refer to data saving specification in Section

9.1.5, “Specifying the Storage Path of the ECG Data”.

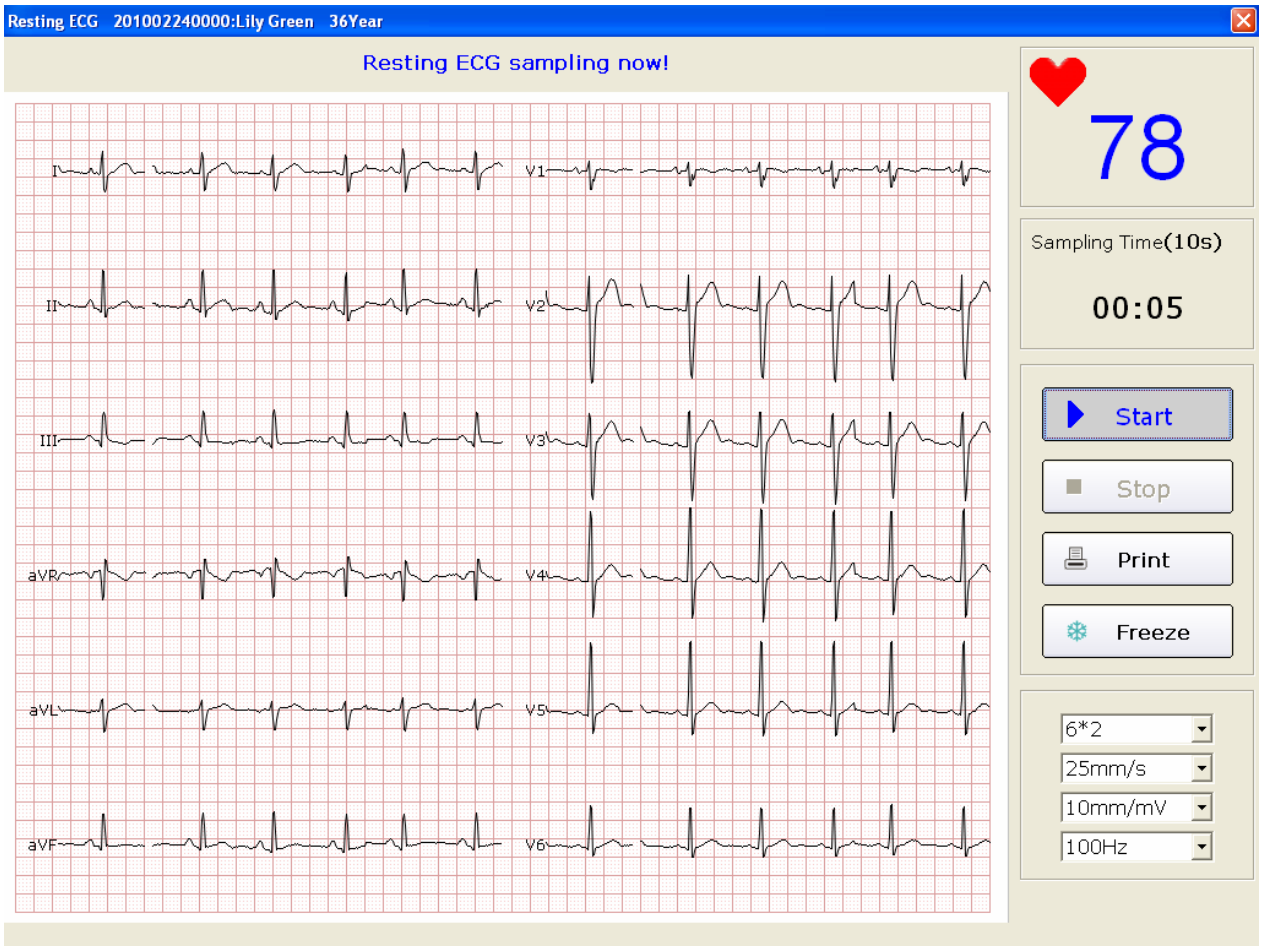


Figure 6-5 ECG Sampling Interface

Note: After you click on the **Start** button, the system will save the sampled ECG data. If you don’t click on the **Start** button, the system won’t save the sampled ECG data.

6.5.6 Freezing and Previewing ECG

Click on the **Freeze** button on the ECG sampling interface (Figure 6-5), the system will display the **Wave review** interface.

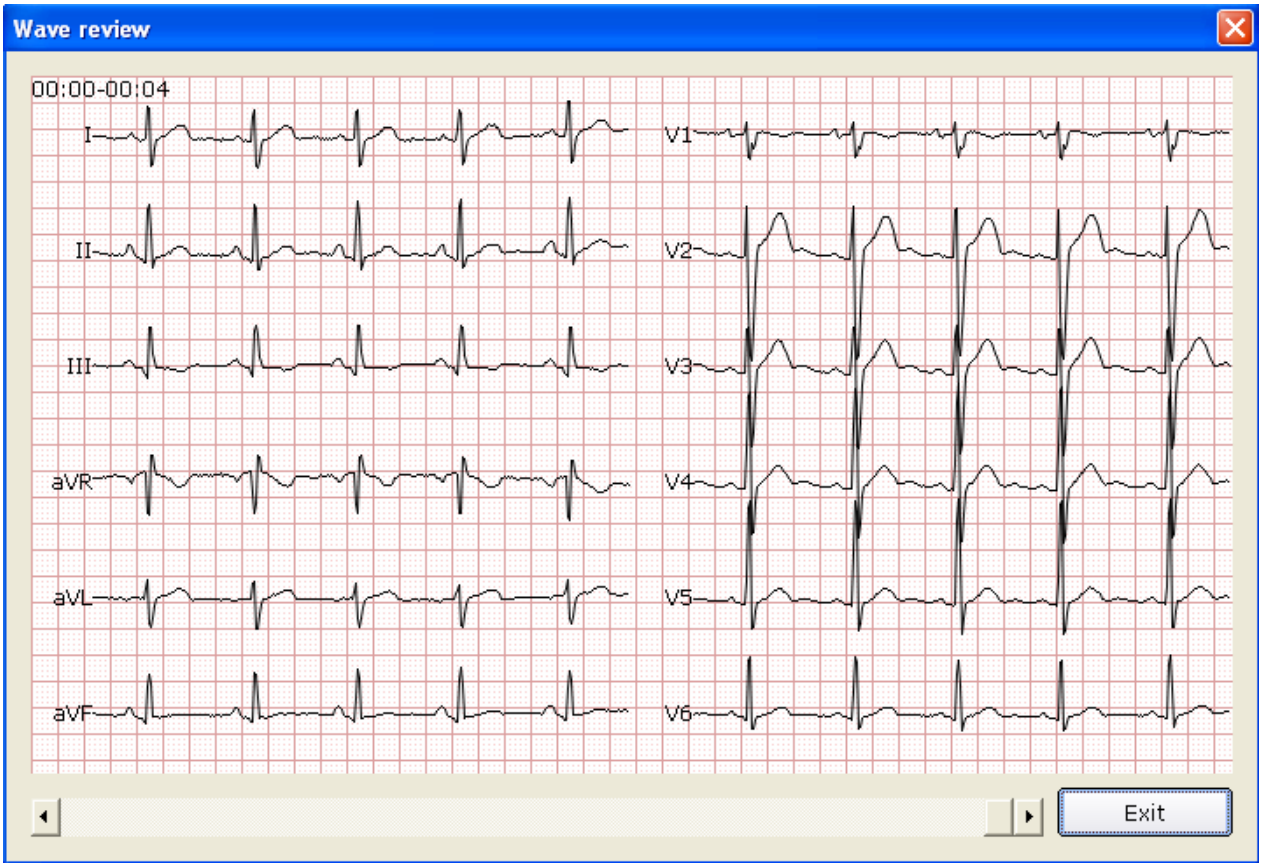


Figure 6-6 Wave Review Interface

Click on **Exit** to return to the ECG sampling interface.

6.5.7 Stopping Sampling Data

After clicking on the **Start** button, there are two ways to stop sampling data.

1. The system will stop sampling ECG data and display the ECG analysis interface automatically after the ECG sampling time is over. For details on setting ECG sampling time, see Section 9.2.2, “Setting Sampling Time”.

2. Before the ECG sampling time is over, you can click on the **Stop** button to stop sampling data and the ECG analysis interface will pop up automatically.

6.5.8 Printing ECG Waves

Click on the **Print** button on the ECG sampling interface to print the ECG waves.

Note: You can set the printer type on the print setup interface. There are two options: **white- black** and **color**. The report color is defined by setting the printer type and can be observed on the preview interface. For details on setting the printer type, see Section 9.4,

"Printer Setup".

6.6 Analyzing ECG Data

You can open the ECG analysis interface in one of the following three ways:

1. Click on the **Start** button, and then the system will stop sampling ECG and display the ECG analysis interface automatically after the ECG sampling time is over.

2. Or click on the **Stop** button to stop sampling after clicking on the **Start** button, and the system will display the ECG analysis interface automatically.

3. Or double-click on an examination record in the examination record list on the **Data Manager** interface (Figure 6-2) to open the ECG analysis interface.

When the sampling type is **Resting ECG**, the ECG analysis interfaces include Normal ECG, QT Dispersion, Frequency ECG and High Frequency ECG (HF ECG).

When the sampling type is **HRV ECG**, the ECG analysis interfaces include Heart Rate Variability and Heart Rate Turbulence.

When the sampling type is **VCG/TVCG/SAECG**, the ECG analysis interfaces include Vector ECG, Time Vector ECG and Signal Averaged ECG.

6.6.1 Analyzing Normal ECG

Click on the **Normal Analysis** button to open the normal ECG analysis interface. There are three tabs: **Waveform**, **Average Template** and **Detail information**.

6.6.1.1 Viewing the Waveform

Click on the **Waveform** tab on the normal ECG analysis interface to open the **Waveform** interface (Figure 6-7).

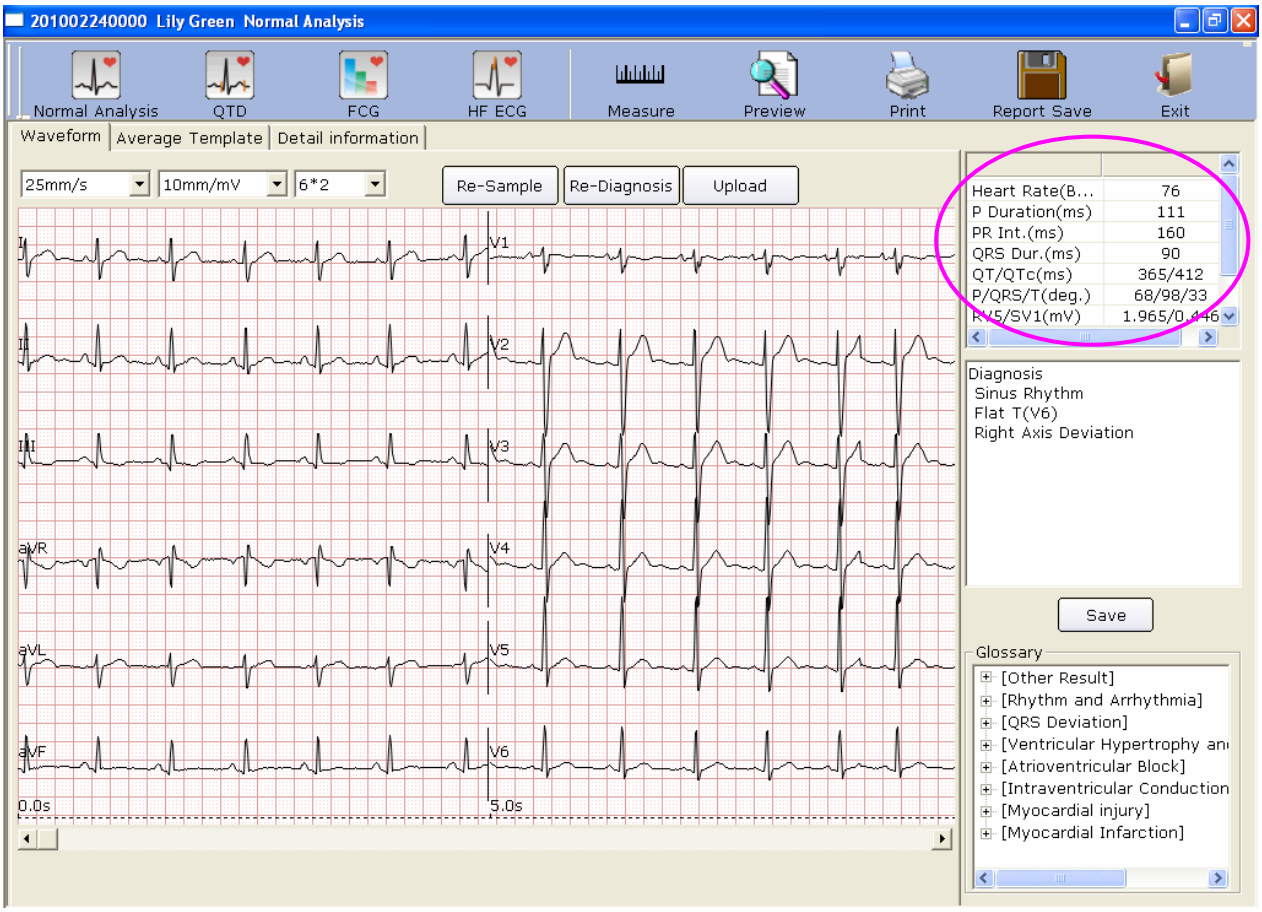


Figure 6-7 Normal ECG - Waveform Interface

You can choose a speed, a gain and a display mode for the displayed waves.

Click on the **Measure** button on the **Waveform** interface (Figure 6-7). Click on one point on the wave, and then drag the mouse to another point. The distance, amplitude difference and heart rate between the two points will be displayed.

Notes:

1. You can measure the distance between any two points more than once after running the ruler. The last measure track and data will be displayed after the measurement.

2. Only ECG waves can be measured.

Click on **Re-Sample**, and then the system can re-sample ECG data.

Click on **Re-Diagnosis**, and then the system can re-diagnose the 10s ECG data on the screen automatically.

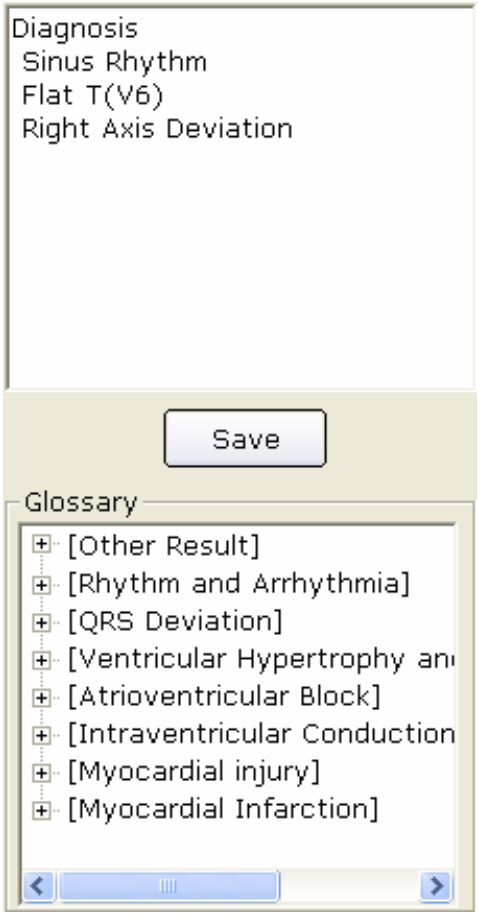
Click on **Upload** to upload the ECG data to ENS.

The common parameters are displayed in the circle in Figure 6-7. These parameters are as follows.

Designation	Description
Heart Rate	Heart Rate
P Duration	P-wave duration of the current lead
PR Dur.	P-R interval of the current lead
QRS Dur.	QRS complex duration of the current lead
QT/QTc	Q-T interval of the current lead/Normalized QT interval
P/QRS/T	Dominant direction of the average integrated ECG vectors
RV5/SV1	The amplitude of R wave of V5 lead/the amplitude of S wave of V1 lead
RV5+SV1	The amplitude of R wave of V5 lead plus the amplitude of S wave of V1 lead
RV6/SV2	The amplitude of R wave of V6 lead/the amplitude of S wave of V2 lead

Double-click on a parameter, and then you can modify it. Then click on the **Save** button to save the modification.

To Edit Diagnosis Result on the Waveform Interface



To Edit the Diagnosis Result

1. Enter your own opinions in the diagnosis textbox, and then click on the **Save** button.

2. Or double-click on the necessary results required to be added in the **Glossary** textbox, and the selected results will be displayed in the diagnosis textbox, and then click on the **Save** button.

6.6.1.2 About the Average Template Interface

Click on the **Average Template** tab on the normal ECG analysis interface to open the average template interface (Figure 6-8). You can analyze average templates on this interface.

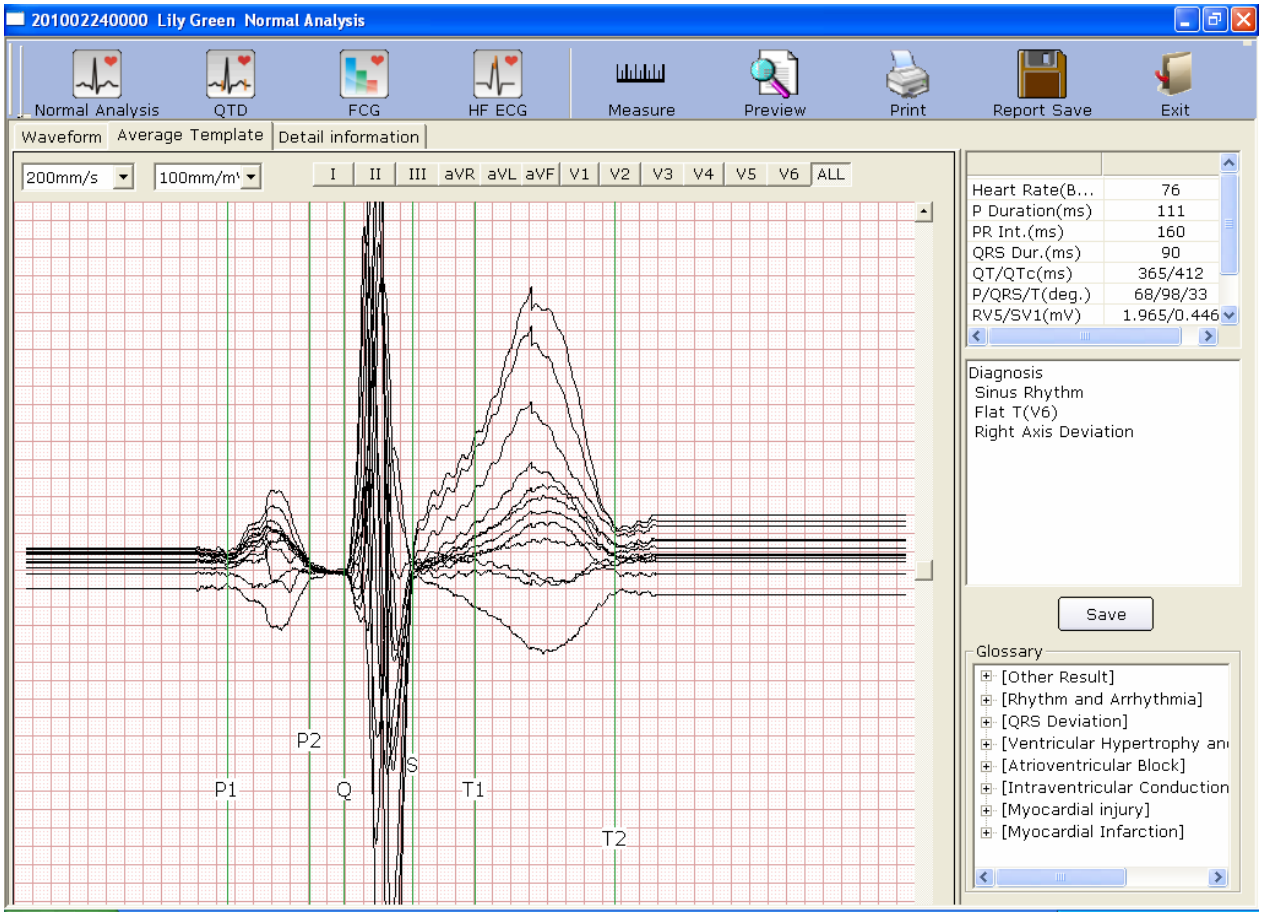
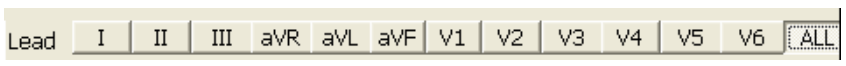


Figure 6-8 Normal ECG – Average Template Interface

To Edit Waveform on the Analysis Interface

You can press a lead button in 

to display magnified average templates of this lead. When you press **ALL**, magnified average templates of all leads will be overlapped with the same central axis.

You can set the speed and the gain of average templates.

You can drag marker lines of P1, P2, Q, S, T1 and T2 on average templates.

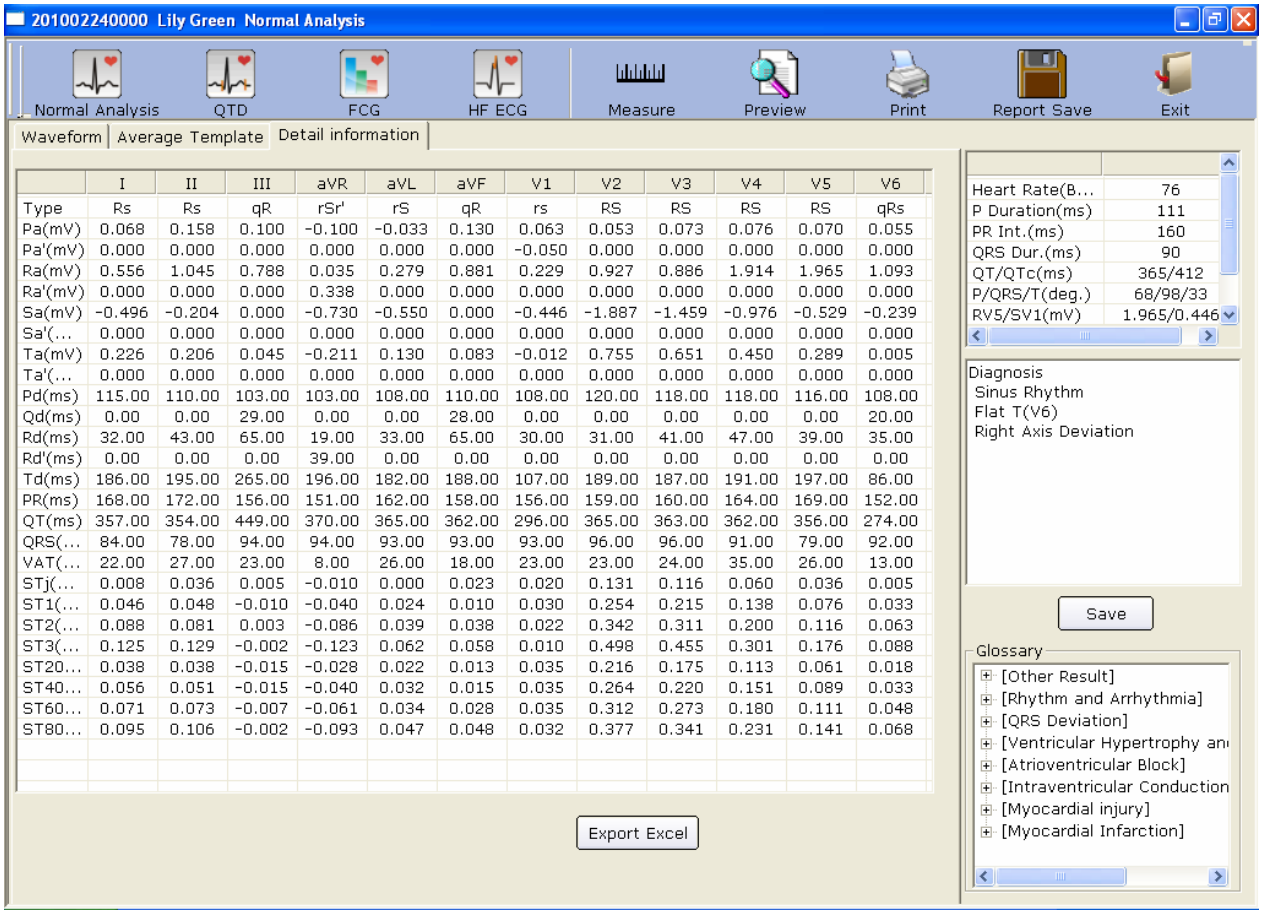
P1 is the start point of P wave, P2 is the end point of P wave, Q marks the position of Q point, S marks the position of S point, T1 is the start point of T wave and T2 is the end point of T wave. Dragging these marks can move these lines, and the corresponding parameter values will change.

To Edit Diagnosis Result on the Average Template Interface

For details, refer to Section 6.6.1.1, "Viewing the Waveform".

6.6.1.3 About the Detail Information Interface

Click on the **Detail information** tab on the normal ECG analysis interface to open the detail information interface. This interface displays lead parameter values as Figure 6-9 shows.



	I	II	III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6
Type	Rs	Rs	qR	rSr'	rS	qR	rs	RS	RS	RS	RS	qRs
Pa(mV)	0.068	0.158	0.100	-0.100	-0.033	0.130	0.063	0.053	0.073	0.076	0.070	0.055
Pa'(mV)	0.000	0.000	0.000	0.000	0.000	0.000	-0.050	0.000	0.000	0.000	0.000	0.000
Ra(mV)	0.556	1.045	0.788	0.035	0.279	0.881	0.229	0.927	0.886	1.914	1.965	1.093
Ra'(mV)	0.000	0.000	0.000	0.338	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Sa(mV)	-0.496	-0.204	0.000	-0.730	-0.550	0.000	-0.446	-1.887	-1.459	-0.976	-0.529	-0.239
Sa'(...	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Ta(mV)	0.226	0.206	0.045	-0.211	0.130	0.083	-0.012	0.755	0.651	0.450	0.289	0.005
Ta'(...	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Pd(ms)	115.00	110.00	103.00	103.00	108.00	110.00	108.00	120.00	118.00	118.00	116.00	108.00
Qd(ms)	0.00	0.00	29.00	0.00	0.00	28.00	0.00	0.00	0.00	0.00	0.00	20.00
Rd(ms)	32.00	43.00	65.00	19.00	33.00	65.00	30.00	31.00	41.00	47.00	39.00	35.00
Rd'(ms)	0.00	0.00	0.00	39.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Td(ms)	186.00	195.00	265.00	196.00	182.00	188.00	107.00	189.00	187.00	191.00	197.00	86.00
PR(ms)	168.00	172.00	156.00	151.00	162.00	158.00	156.00	159.00	160.00	164.00	169.00	152.00
QT(ms)	357.00	354.00	449.00	370.00	365.00	362.00	296.00	365.00	363.00	362.00	356.00	274.00
QRS(...	84.00	78.00	94.00	94.00	93.00	93.00	93.00	96.00	96.00	91.00	79.00	92.00
VAT(...	22.00	27.00	23.00	8.00	26.00	18.00	23.00	23.00	24.00	35.00	26.00	13.00
STj(...	0.008	0.036	0.005	-0.010	0.000	0.023	0.020	0.131	0.116	0.060	0.036	0.005
ST1(...	0.046	0.048	-0.010	-0.040	0.024	0.010	0.030	0.254	0.215	0.138	0.076	0.033
ST2(...	0.088	0.081	0.003	-0.086	0.039	0.038	0.022	0.342	0.311	0.200	0.116	0.063
ST3(...	0.125	0.129	-0.002	-0.123	0.062	0.058	0.010	0.498	0.455	0.301	0.176	0.088
ST20...	0.038	0.038	-0.015	-0.028	0.022	0.013	0.035	0.216	0.175	0.113	0.061	0.018
ST40...	0.056	0.051	-0.015	-0.040	0.032	0.015	0.035	0.264	0.220	0.151	0.089	0.033
ST60...	0.071	0.073	-0.007	-0.061	0.034	0.028	0.035	0.312	0.273	0.180	0.111	0.048
ST80...	0.095	0.106	-0.002	-0.093	0.047	0.048	0.032	0.377	0.341	0.231	0.141	0.068

Figure 6-9 Normal ECG - Detail Information Interface

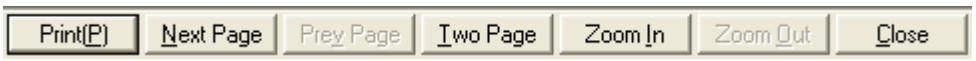
Click on the **Export Excel** button to export an Excel file.

To Edit Diagnosis Result on the Detail Information Interface

For details, refer to Section 6.6.1.1, "Viewing the Waveform".

6.6.1.4 Previewing Normal ECG

Click on the **Preview** button to display the normal ECG preview interface.



is the toolbar on the normal ECG preview interface.

1. Click on the **Next Page** button on the toolbar to switch to the next preview page.
2. Click on the **Two Page** button on the toolbar to preview two pages on one screen simultaneously.
3. Click on the **Zoom In** button on the toolbar to magnify the preview page.
4. Click on the **Zoom Out** button on the toolbar to minify the preview page.
5. Click on the **Close** button to close the normal ECG preview interface and return to the previous interface.

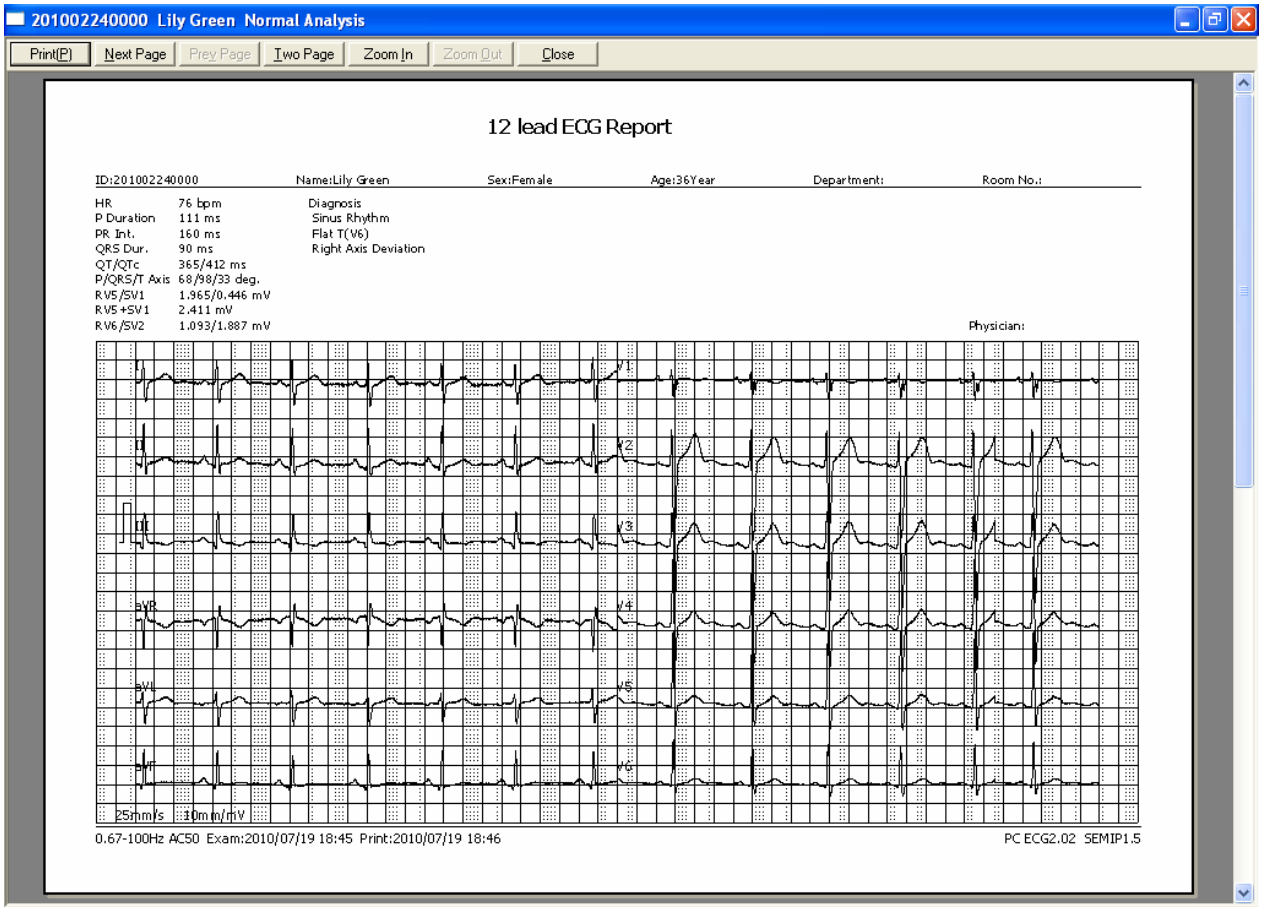


Figure 6-10 ECG Wave - the First Page

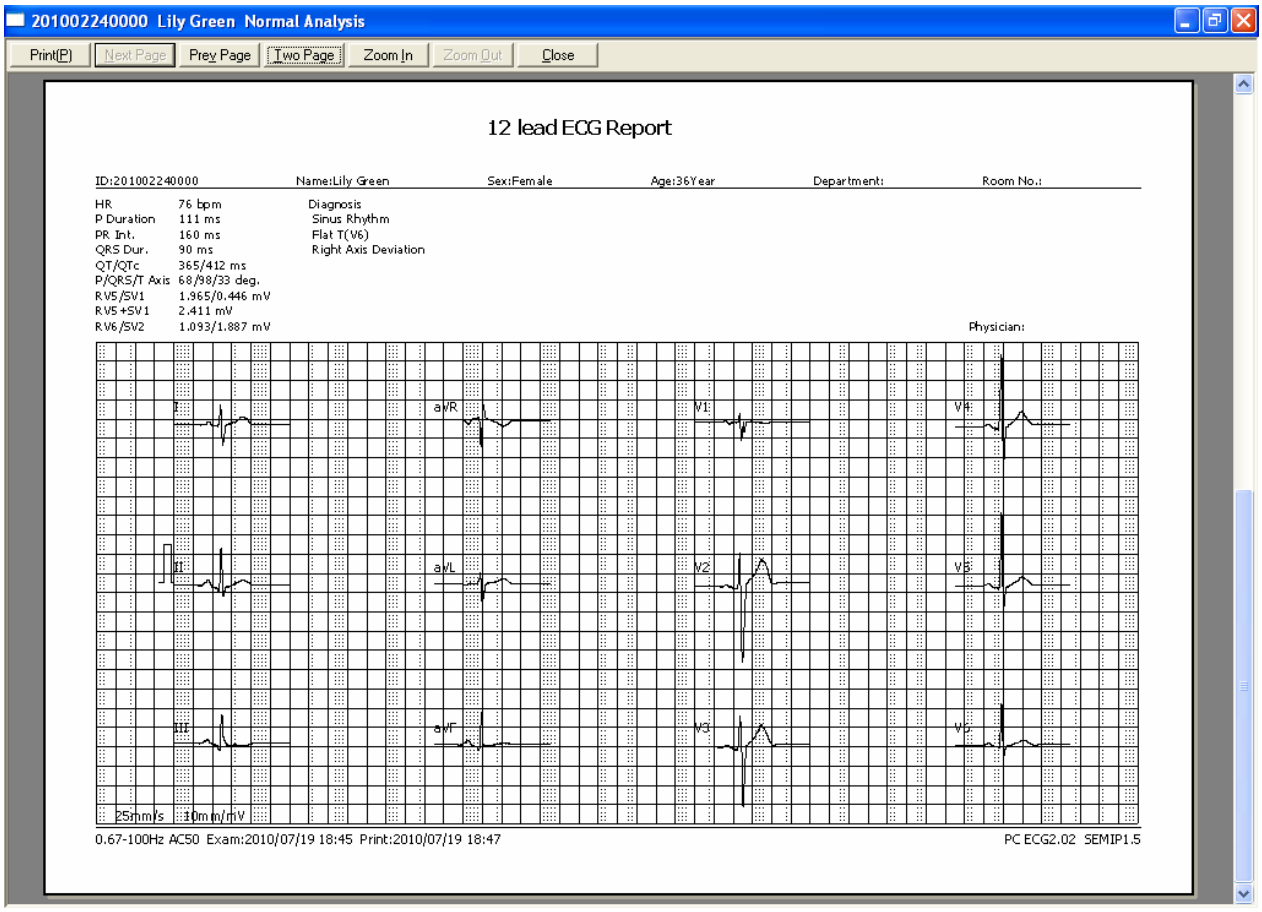


Figure 6-11 Average Template & Position Marker - the Second Page

6.6.2 Analyzing QT Dispersion

Click on the **QT Dispersion** button to open the QT Dispersion interface.

QT Dispersion: The difference between the largest QT interval and the shortest QT interval based on the synchronous 12-lead surface ECG. The QT interval is a measurement of the time difference between the start of the Q wave and the end of the T wave.

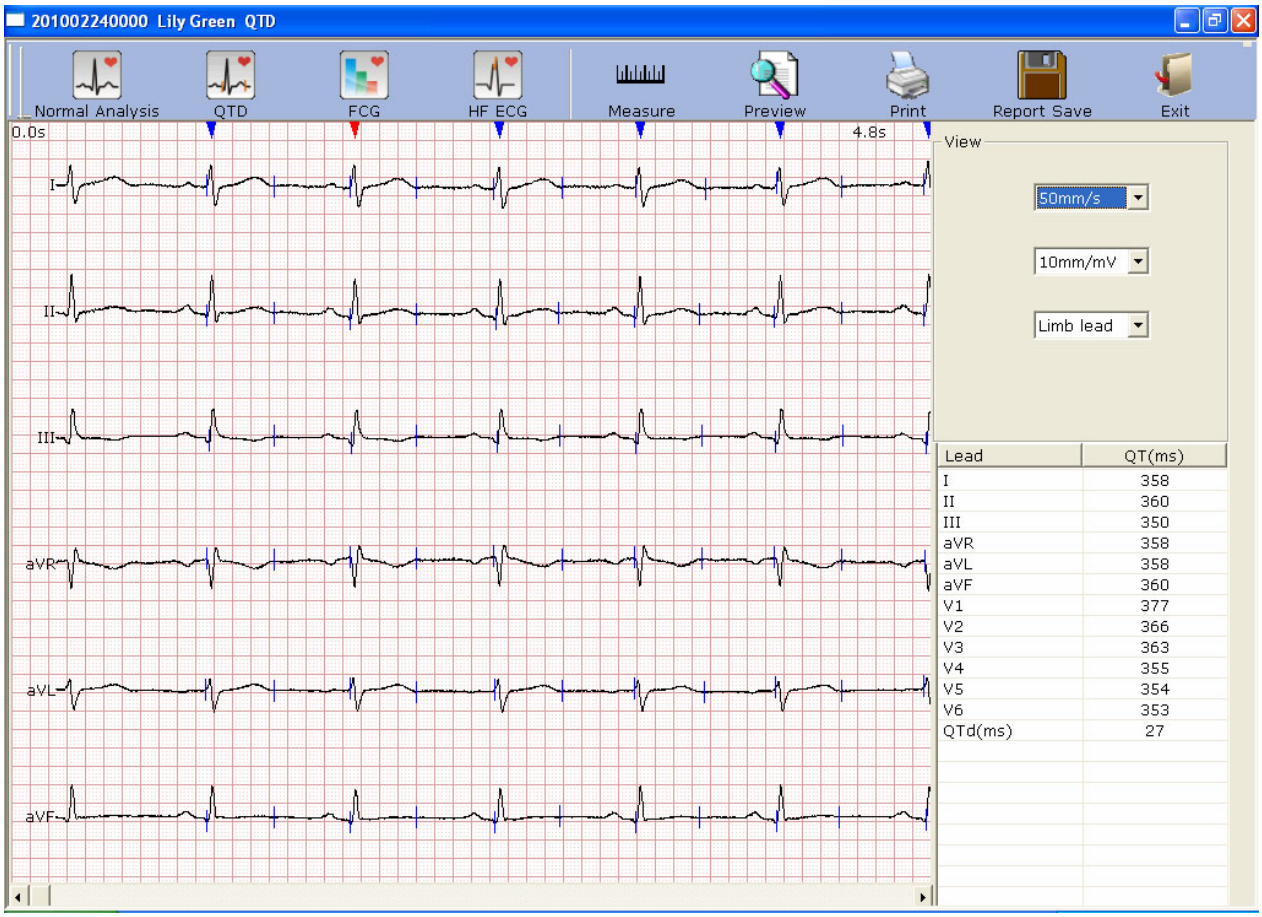


Figure 6-12 QT Dispersion Interface

6.6.2.1 Editing Waveform on the QT Dispersion Interface

There are red and blue triangle icons on top of the displayed ECG waves. You can click on the triangle icon to change the color.

represents the current chosen R wave

represents the position of R wave

You can set the speed and the gain of the displayed ECG waves. The lead number and the lead type of the displayed ECG waves can also be chosen.

6.6.2.2 About QT Value

Lead	QT(ms)
I	358
II	360
III	350
aVR	358
aVL	358
aVF	360
V1	377
V2	366
V3	363
V4	355
V5	354
V6	353
QTd(ms)	27

QT values of 12 leads and QT dispersion (QTd) are displayed as the left figure shows.

6.6.2.3 Previewing QT Dispersion

Click on the **Preview** button on the QT Dispersion interface to open the QT Dispersion preview interface.

is the toolbar on the QT Dispersion preview interface.

1. Click on the **Zoom In** button on the toolbar to magnify the preview page.

2. Click on the **Zoom Out** button on the toolbar to minify the preview page.

3. Click on the **Close** button to close the QT Dispersion preview interface and return to the previous interface.

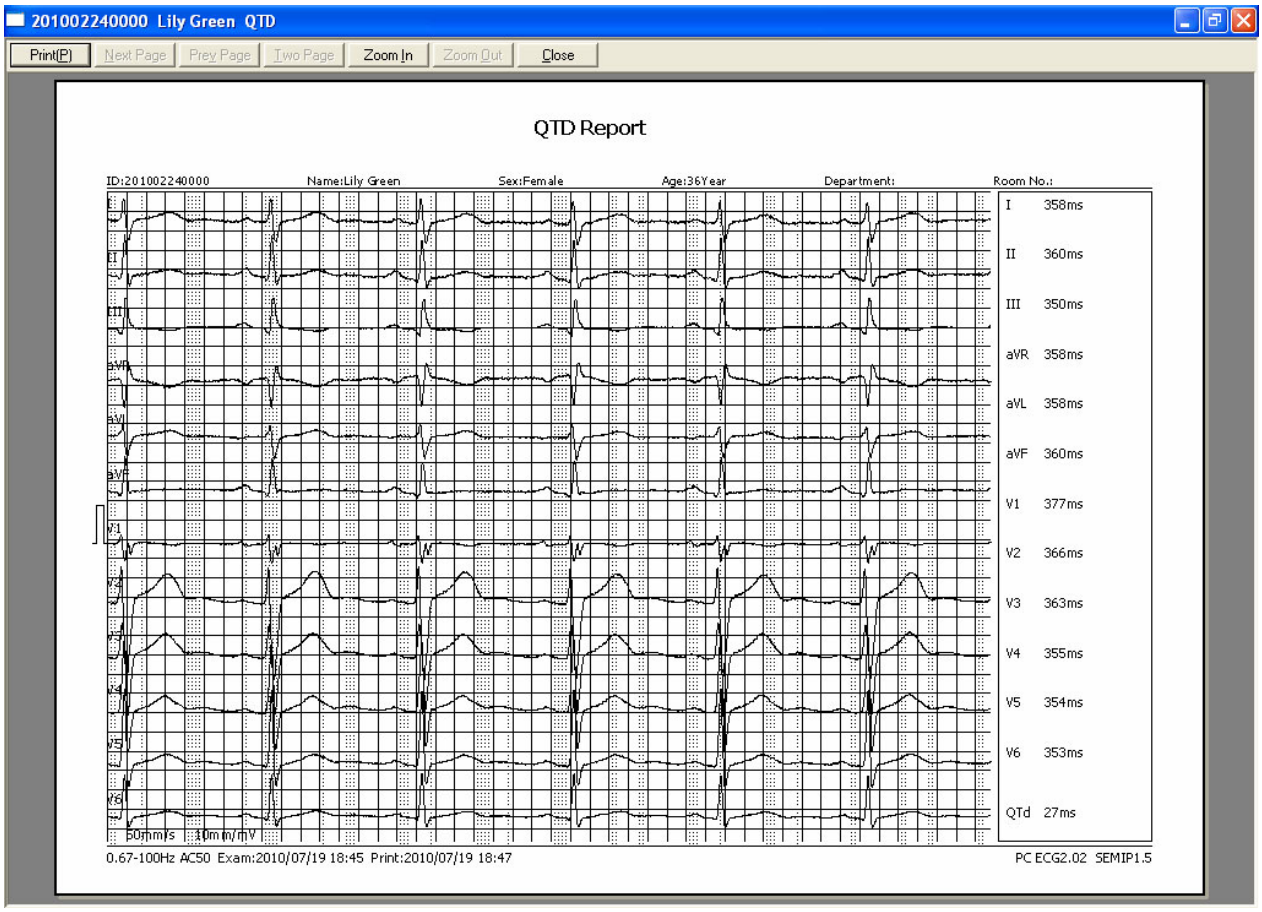


Figure 6-13 QT Dispersion Preview Interface

6.6.3 Analyzing Frequency ECG

Click on the **Frequency ECG** button to open the Frequency ECG interface.
Frequency ECG displays characteristic waves of ECG signal spectrum.
There are two tabs on the Frequency ECG interface: **Two leads compare** and **12-lead power spectrum**.

6.6.3.1 About Two-lead Comparison Interface

The two-lead comparison interface displays the power spectrum, phase shift, amplitude shift, coherence, impulse response and correlation functions of ECG waves, as Figure 6-14 shows.

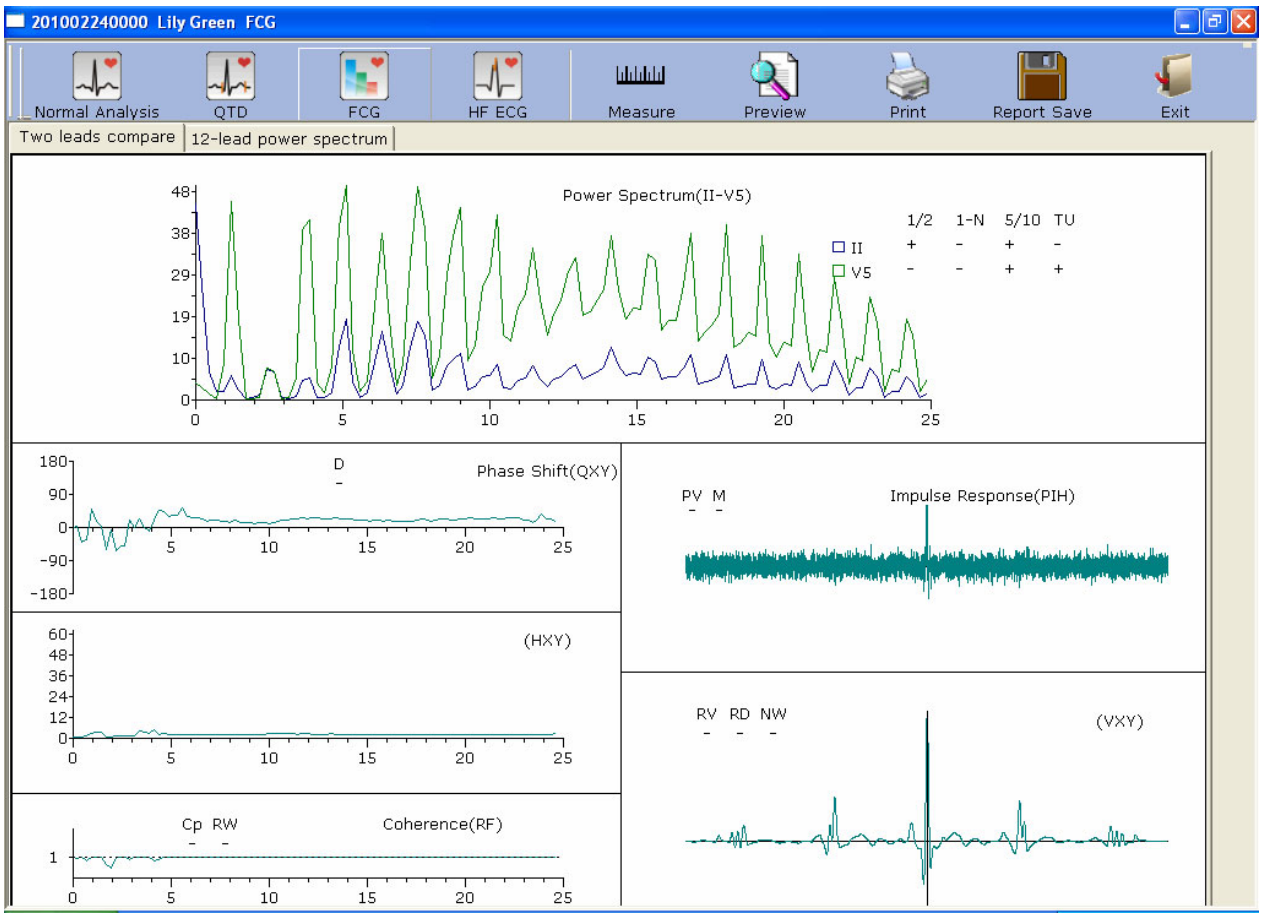


Figure 6-14 Frequency ECG - Two-lead Comparison Interface

Every parameter of Frequency ECG is shown in the following table.

	Designation	**Definition**
Power Spectrum	1/2	If the first peak value is lower than 90% of the second peak value, it is positive (‘+’). Otherwise it is minus (‘-’).
	1-N	The first peak is too low or disappears. (The frequency value of the first peak’s position * 60 = heart rate. For example, if the frequency value of the first peak’s position is 1.2, the heart rate is 72.)
	5/10	If the peak value of any peak behind the fifth peak is higher than the first peak value, it is positive. Otherwise it is minus.
	TU	If the distances between peak values are not equal, it is positive. Otherwise it is minus.

Phase Shift	D	If the phase shift in the range of 6~18Hz exceeds 90 degrees, it is positive. Otherwise it is minus.
Coherence	Cp	If the coherence value of the fundamental (the position of the first peak in power spectrum) is less than 0.8, it is positive. Otherwise it is minus.
	RW	If there are four twists and turns with peak-to-valley interval >0.5r or five twists and turns with peak-to-valley interval >0.1 in the range of 10~20Hz, it is positive. Otherwise it is minus.
Impulse Response	PV	If the main peak in the middle upends, the downward peak value is higher than the upward peak value, it is positive. Otherwise it is minus.
	M	If there is a peak around the main peak higher than 60% of the main peak, it is positive. Otherwise it is minus.
Correlation Function (VXY)	RV	If the main peak in the middle upends, it is positive. Otherwise it is minus.
	RD	If the main peak in the middle deviates from the origin and the baseline, it is positive. Otherwise it is minus.
	NW	The main peak is like the letter ‘N’.

6.6.3.2 About 12-lead Power Spectrum Interface

The **12-lead power spectrum** interface displays the power spectrum of 12-lead ECG waves.

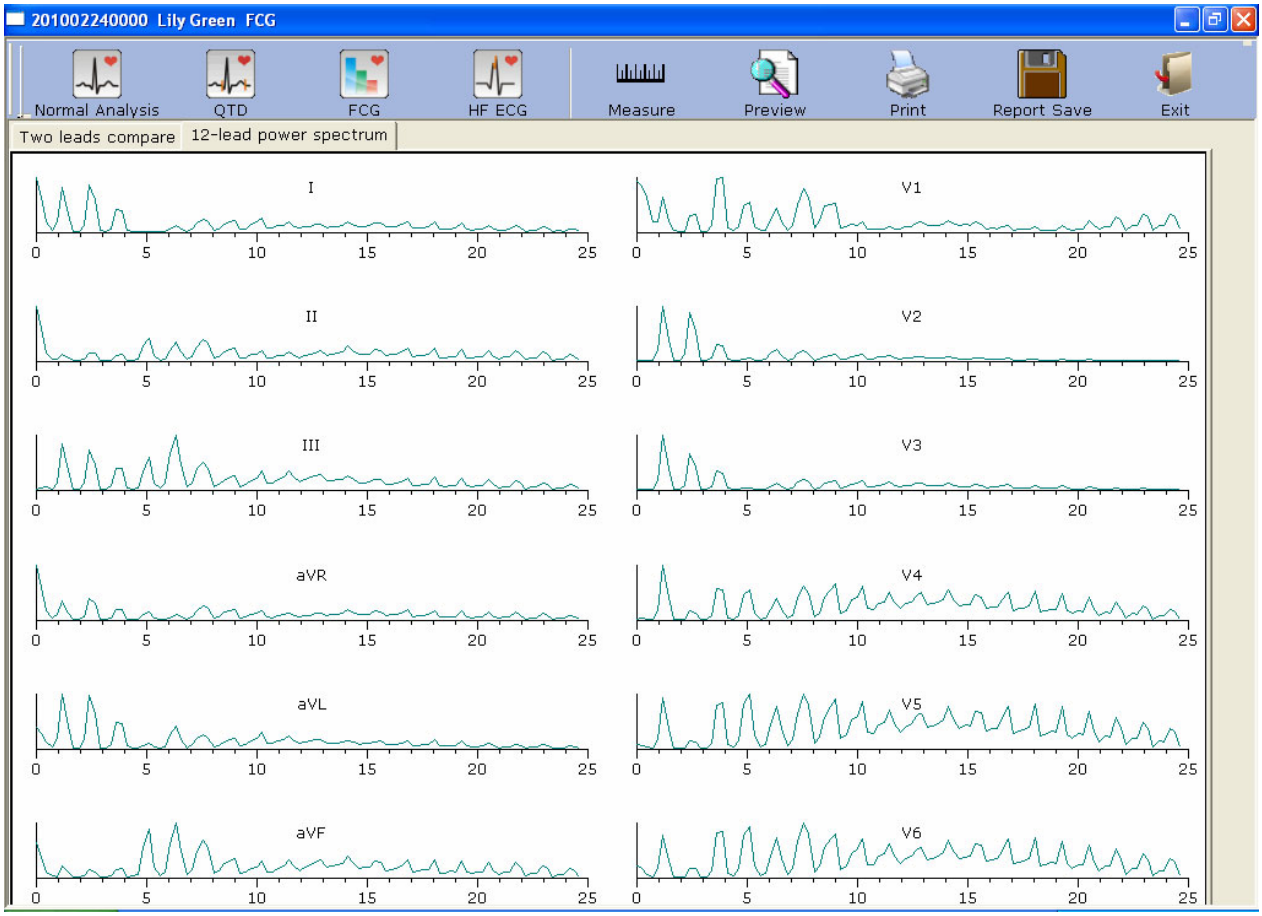


Figure 6-15 Frequency ECG - 12-lead Power Spectrum

6.6.3.3 Previewing Frequency ECG

Click on the **Preview** button to open the Frequency ECG preview interface.

is the toolbar on the Frequency ECG preview interface.

1. Click on the **Zoom In** button on the toolbar to magnify the preview page.
2. Click on the **Zoom Out** button on the toolbar to minify the preview page.
3. Click on the **Close** button to close the Frequency ECG preview interface and return to the previous interface.

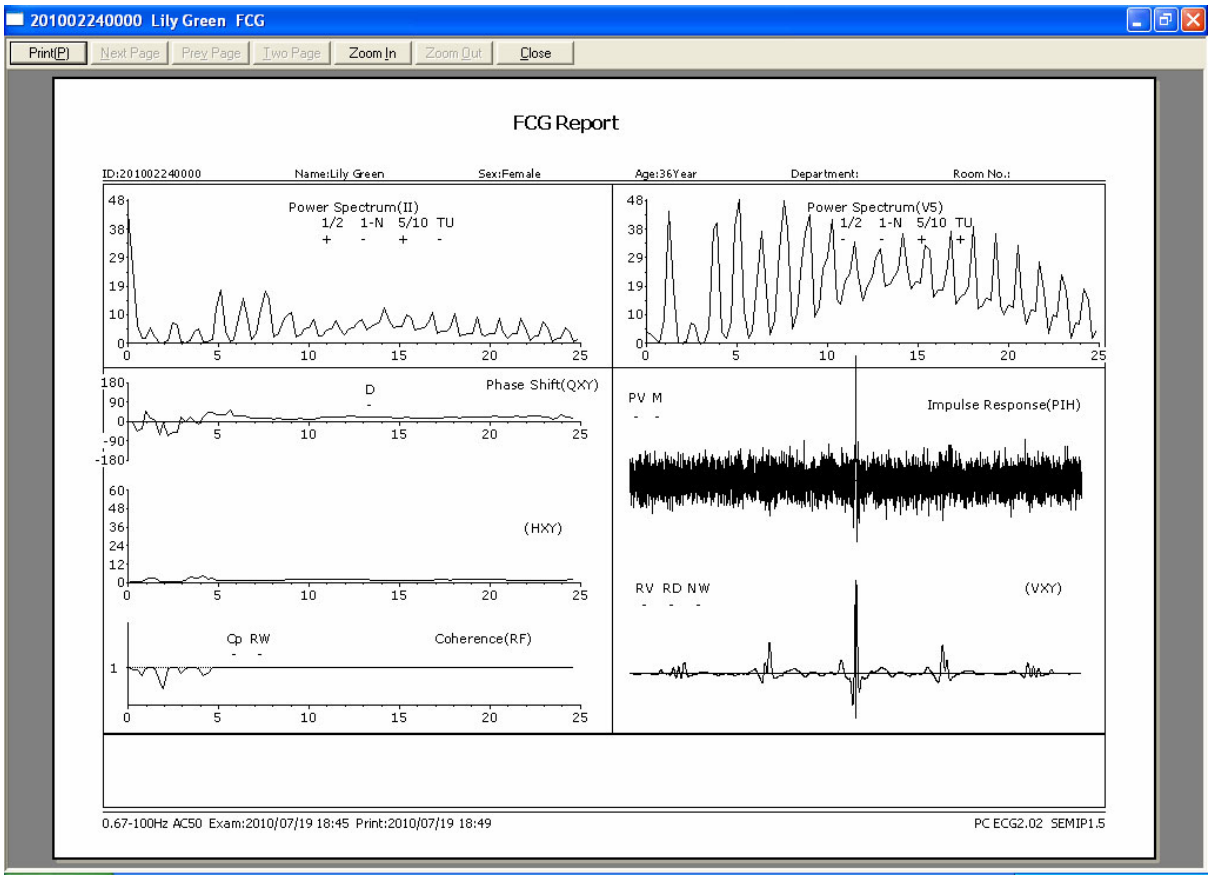


Figure 6-16 Two-lead Comparison Report

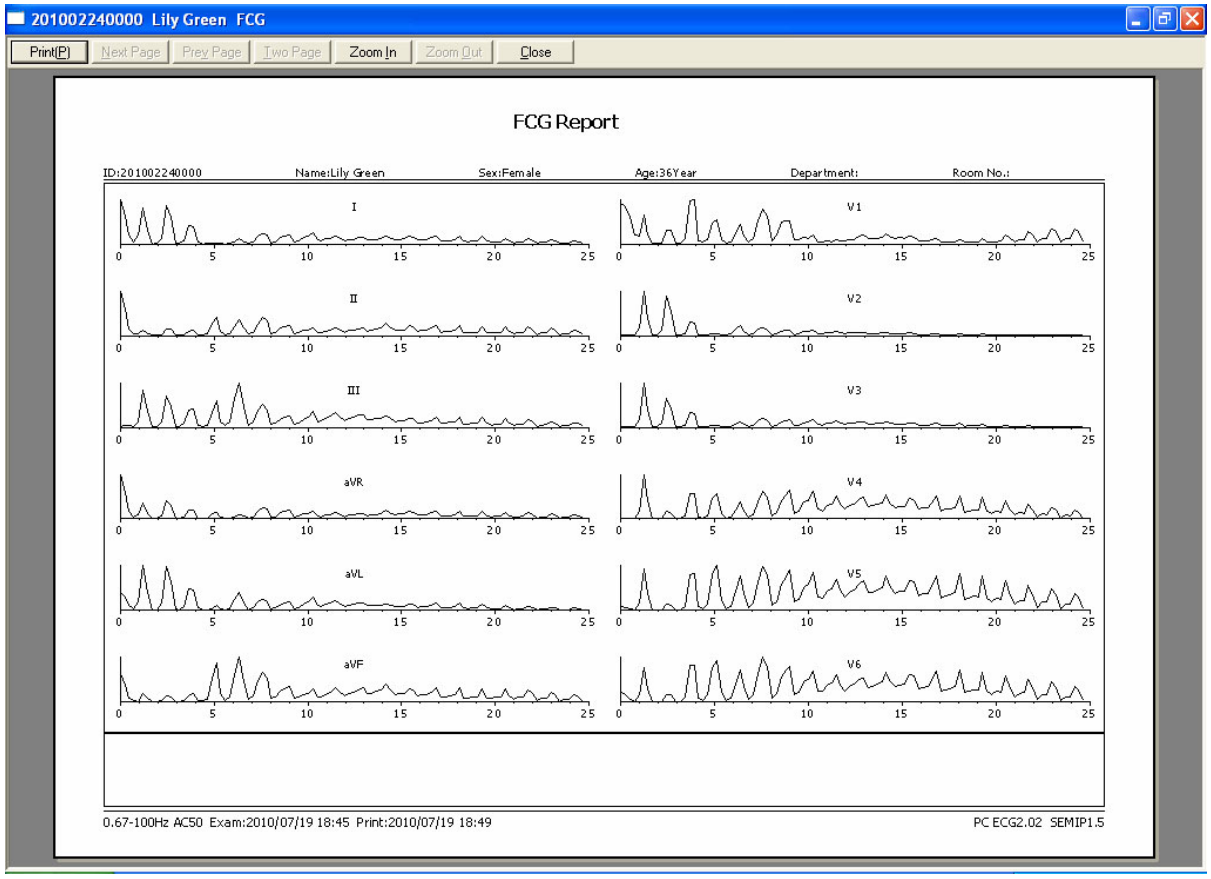


Figure 6-17 12-lead Power Spectrum Report

6.6.4 Analyzing High Frequency ECG

In a conventional electrocardiogram, only these ECG signals, of which the amplitude is in the millivolt range and the frequency is less than 100 Hz, are visible. Those ECG signals, of which the amplitude is in the microvolt range and the frequency is between 150Hz and 250Hz, are invisible. If these invisible high frequency components are abnormal, it is the indication of myocardial ischemia or myocardial infarction.

HF ECG is to detect high frequency components of QRS such as notches, slurs and beadings.

Click on the **HF ECG** button to open the HF ECG analysis interface.

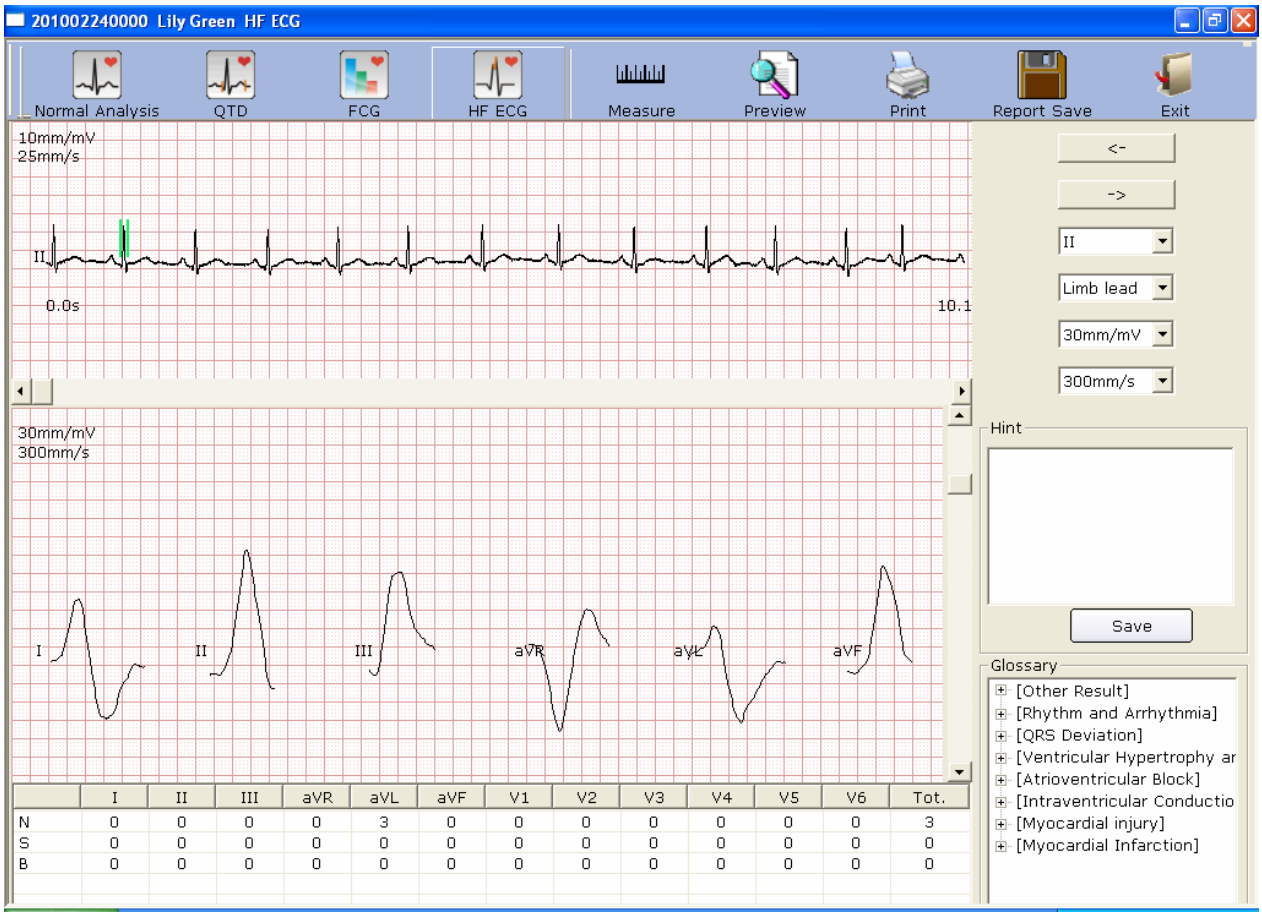
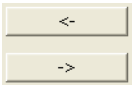
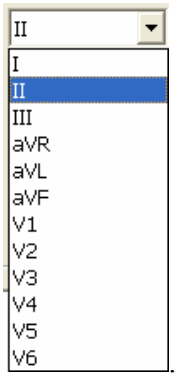


Figure 6-18 HF ECG Analysis Interface

The ECG wave between the two green lines is the present one.

Click on  to select other ECG waves. Select the present lead in the pull-down list



You can choose the lead group, the gain and the speed of the waves displayed in the bottom part of the HF ECG analysis interface.

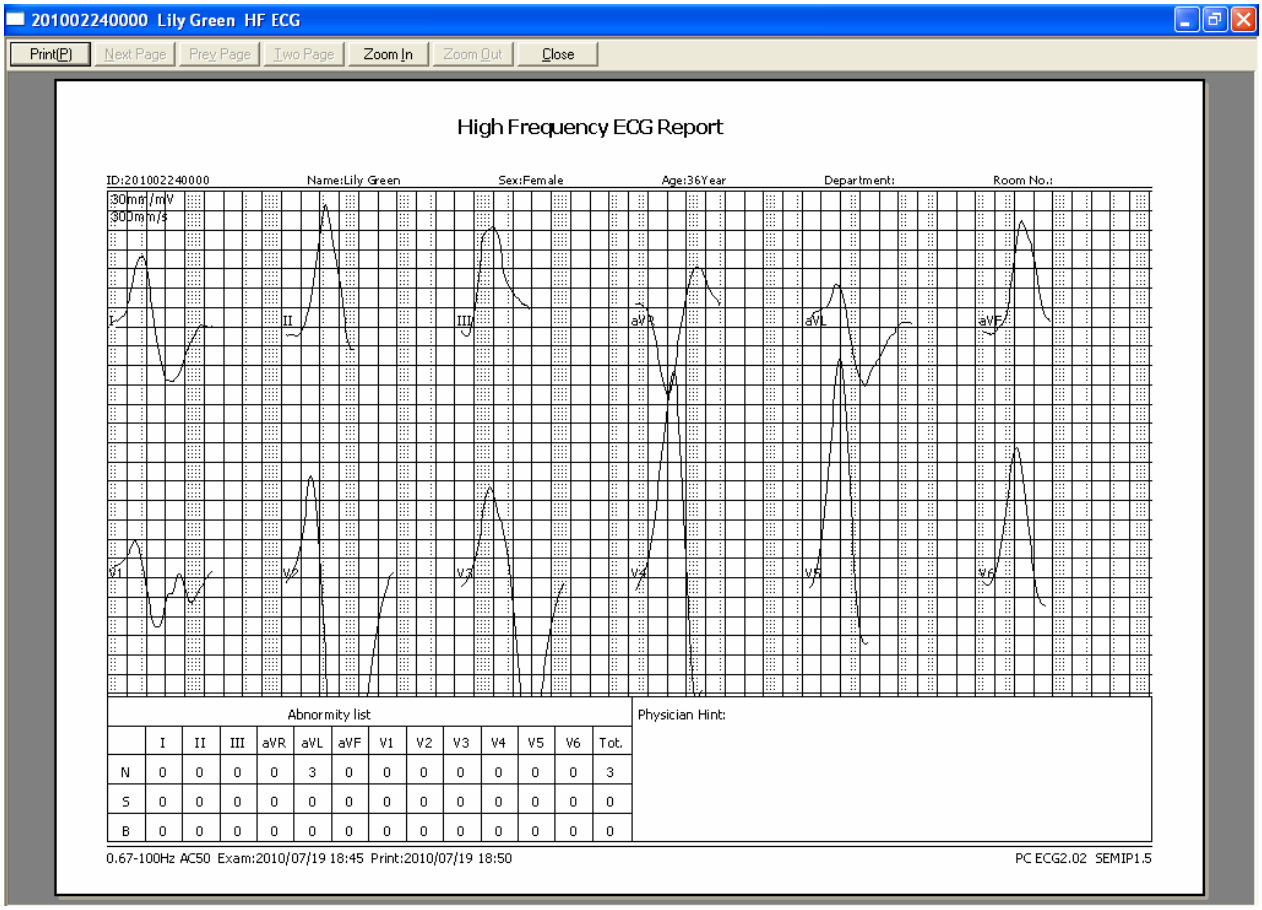
	I	II	III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6	Tot.
N	0	0	0	0	3	0	0	0	0	0	0	0	3
S	0	0	0	0	0	0	0	0	0	0	0	0	0
B	0	0	0	0	0	0	0	0	0	0	0	0	0

is the statistic data of beadings, notches and slurs. You can change a value by double-clicking on the value.

Click on the **Preview** button to open the HF ECG preview interface.

is the toolbar on the HF ECG preview interface.

1. Click on the **Zoom In** button on the toolbar to magnify the preview page.
2. Click on the **Zoom Out** button on the toolbar to minify the preview page.
3. Click on the **Close** button to close the HF ECG preview interface and return to the previous interface.



	I	II	III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6	Tot.
N	0	0	0	0	3	0	0	0	0	0	0	0	3
S	0	0	0	0	0	0	0	0	0	0	0	0	0
B	0	0	0	0	0	0	0	0	0	0	0	0	0

Figure 6-19 HF ECG Report

6.6.5 Analyzing HRV

Click on **HRV** to display the HRV ECG analysis interface. The HRV ECG analysis interface includes two tabs: **Auto diagnosis result** and **Waveform**.

Notes:

1. The HRV sampling time can be set on the sample setup interface.
2. The HRV analysis lead can be selected on the sample setup interface.

6.6.5.1 Editing the HRV Data on the Analysis Interface

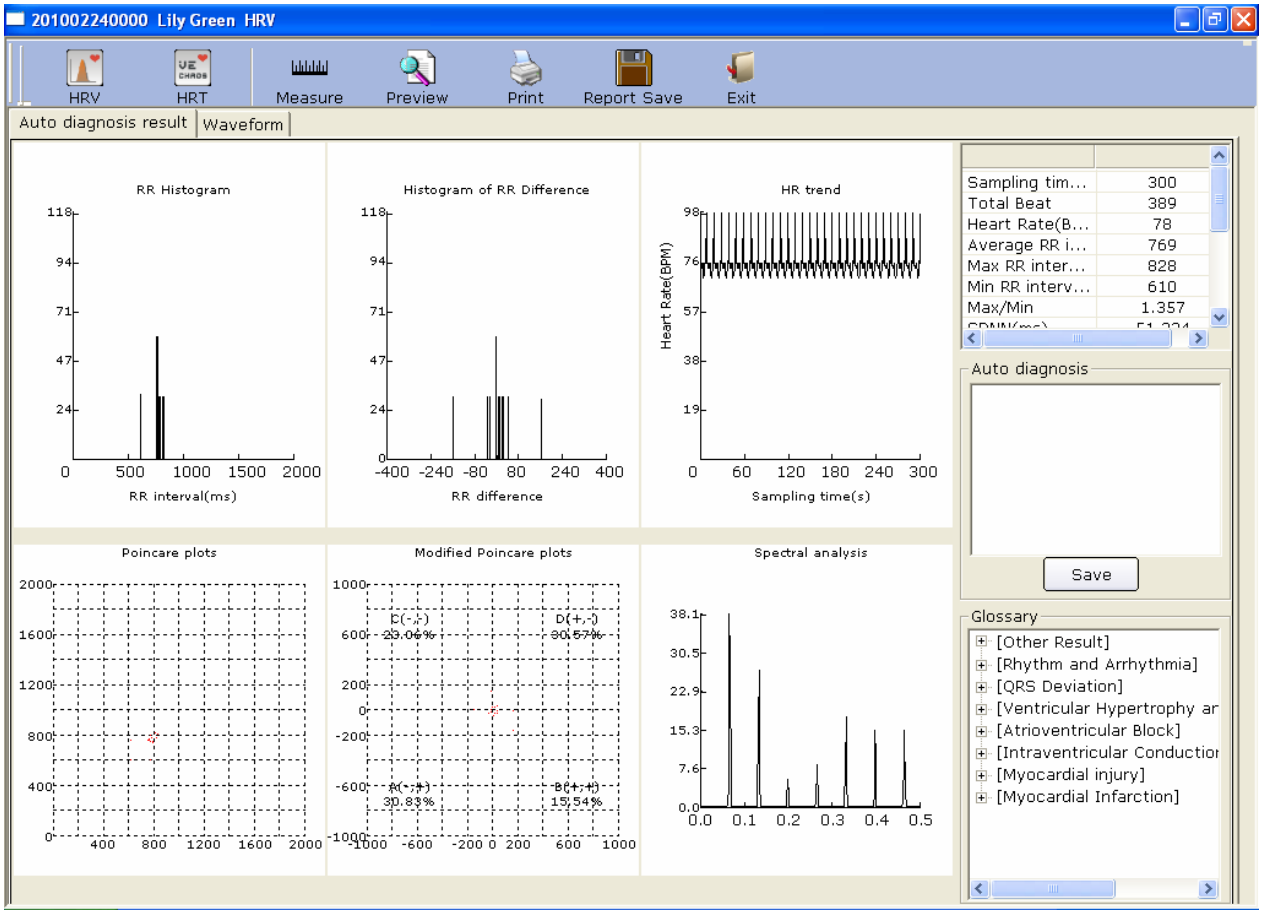


Figure 6-20 Analysis Interface of HRV

Designation	Definition
Sampling time	Set sampling time
Total Beat	Total beat number during the measuring course
Heart Rate	Heart rate
Average RR interval	Average RR interval
Max RR interval	Maximum RR interval
Min RR interval	Minimum RR interval
Max/Min	Ratio of Maximum RR interval to Minimum RR interval
SDNN	Standard Deviation of Normal to Normal Intervals
RMSSD	Root Mean Square Successive Difference
LF	Low Frequency
HF	High Frequency
LF/HF	Ratio of low frequency to high frequency

LF (norm)	Standard LF power
HF (norm)	Standard HF power

H- Doctor Diagnosis Field

1. Enter your own opinions in the **Auto diagnosis** textbox, and then click on the **Save** button.

2. Or double-click on the necessary results required to be added in the **Glossary** textbox, and the selected results will be displayed in the **Auto Diagnosis** textbox, and then click on the **Save** button.

6.6.5.2 Editing the HRV Waveform on the Waveform Interface

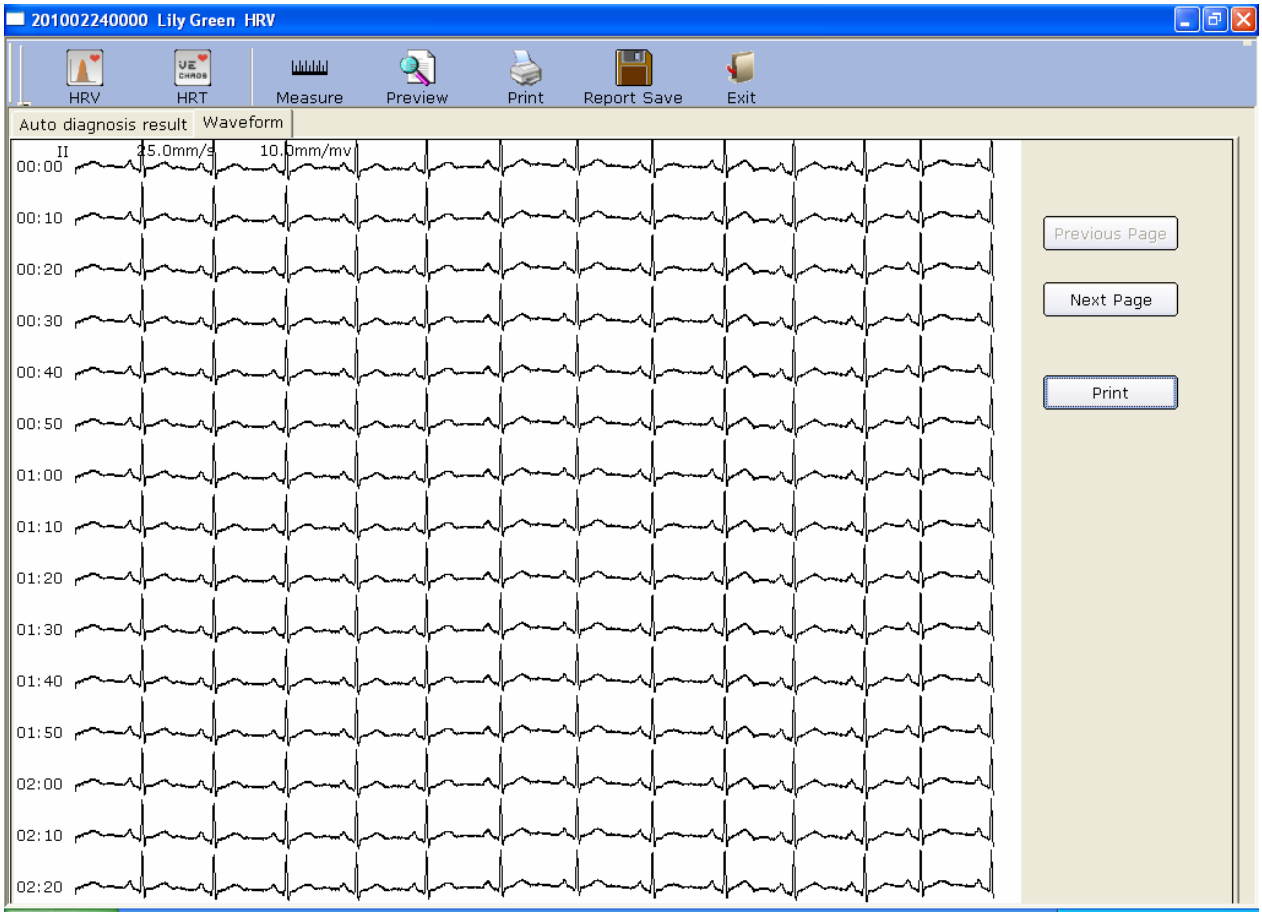


Figure 6-21 Waveform Interface of HRV

HRV waveform is displayed on the **Waveform** interface (Figure 6-21).

1. You can drag the mouse on the interface to choose the wave field to be printed. Then click on the **Print** button to print the selected wave field.

2. Click on **Previous Page** or **Next Page** to display the waves of the previous or next page.

6.6.5.3 Previewing HRV

Click on the **Preview** button to open the HRV preview interface.

is the toolbar on the HRV preview interface.

1. Click on the **Zoom In** button on the toolbar to magnify the preview page.
2. Click on the **Zoom Out** button on the toolbar to minify the preview page.
3. Click on the **Close** button to close the HRV preview interface and return to the previous interface.

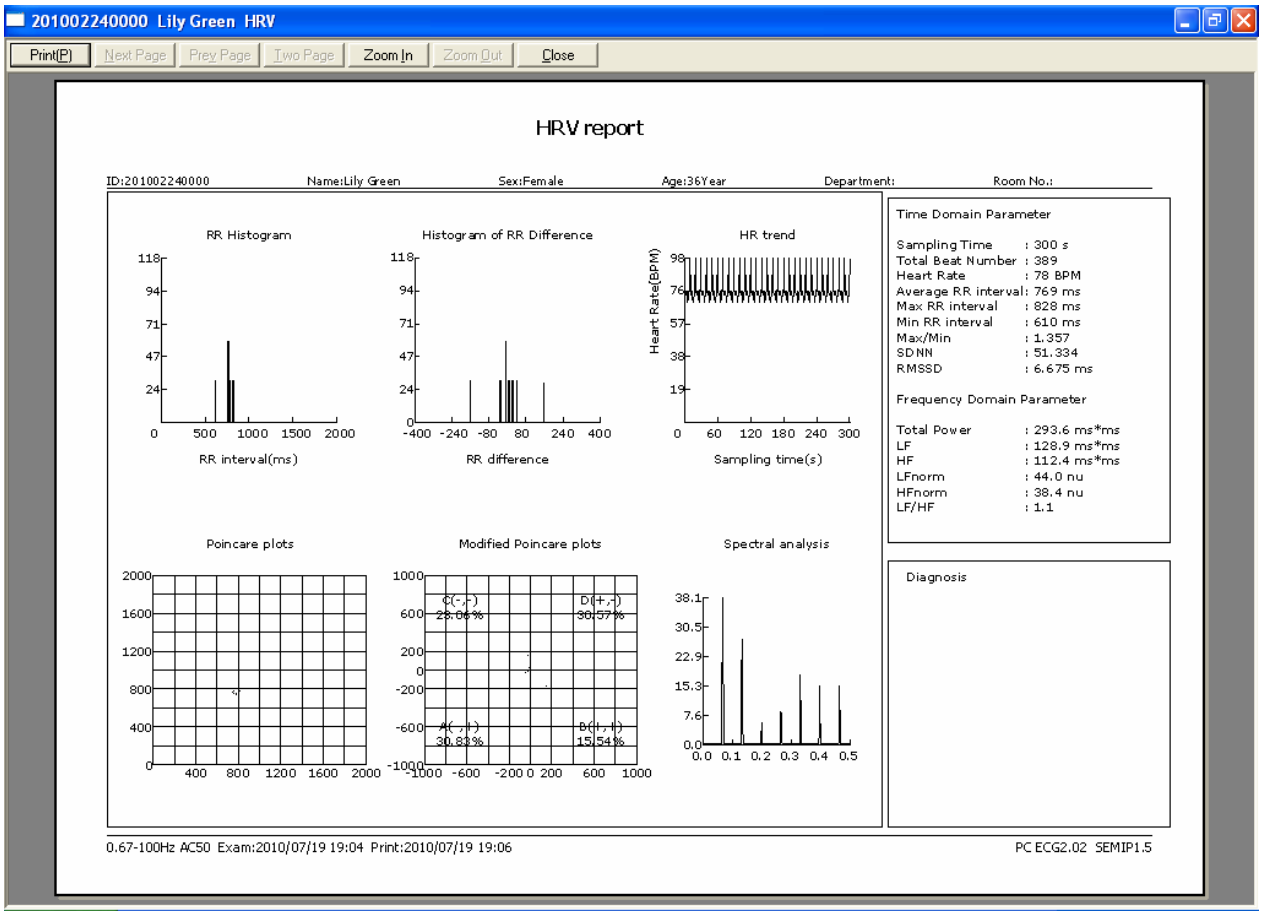


Figure 6-22 HRV Preview Interface - the First Page

6.6.5.4 Printing HRV Wave

Click on one point on the wave and then drag the mouse to another point on the **Waveform** interface (Figure 6-21). Then click on **Print** to print the selected range.

6.6.6 Analyzing HRT

Heart Rate Turbulence (HRT) is a physiological, biphasic response of the sinus node to the premature ventricular contractions. It includes a short initial acceleration followed by a deceleration of the heart rate. HRT can be quantified by two numerical parameters, namely, the Turbulence Onset and the Turbulence Slope.

Turbulence Onset (TO)

Turbulence Onset (TO) is the percentage difference between the heart rate after PVC and the heart rate before PVC. It is calculated by using the equation TO = ((RR1 + RR2) - (RR-2 + RR-1)) / (RR-2 + RR-1) * 100. RR-2 and RR-1 are the last two normal intervals before PVC and RR1 and RR2 are the first two normal intervals after PVC. Positive values of Turbulence Onset indicate the deceleration, while negative values indicate the acceleration of the sinus rhythm.

Turbulence Slope (TS)

Turbulence Slope (TS) corresponds to the steepest slope of the linear regression line for each sequence of five consecutive normal intervals in the local tachogram. The Turbulence Slope calculations are based on the averaged tachogram and expressed in ms per RR interval.

Filters

The algorithm of HRT quantification can deliver usable results only if the triggering event is a true PVC (not an artifact, T-wave or similar). In addition, the sinus rhythms just before and after PVC must be free from arrhythmia, artifacts and false classifications. In order to fulfill these requirements, we use filters which exclude RR intervals with the following characteristics from the HRT calculation:

- <300ms
- >2000ms
- >200ms difference to the preceding sinus interval
- >20% difference to the reference interval (mean of the last 5 sinus intervals)

In addition, we limit the HRT calculations to PVCs with:

- a minimum prematurity of 20% and
- a post-extrasystole interval which is at least 20% longer than the normal interval.

Click on **HRT** to display the HRT analysis interface.

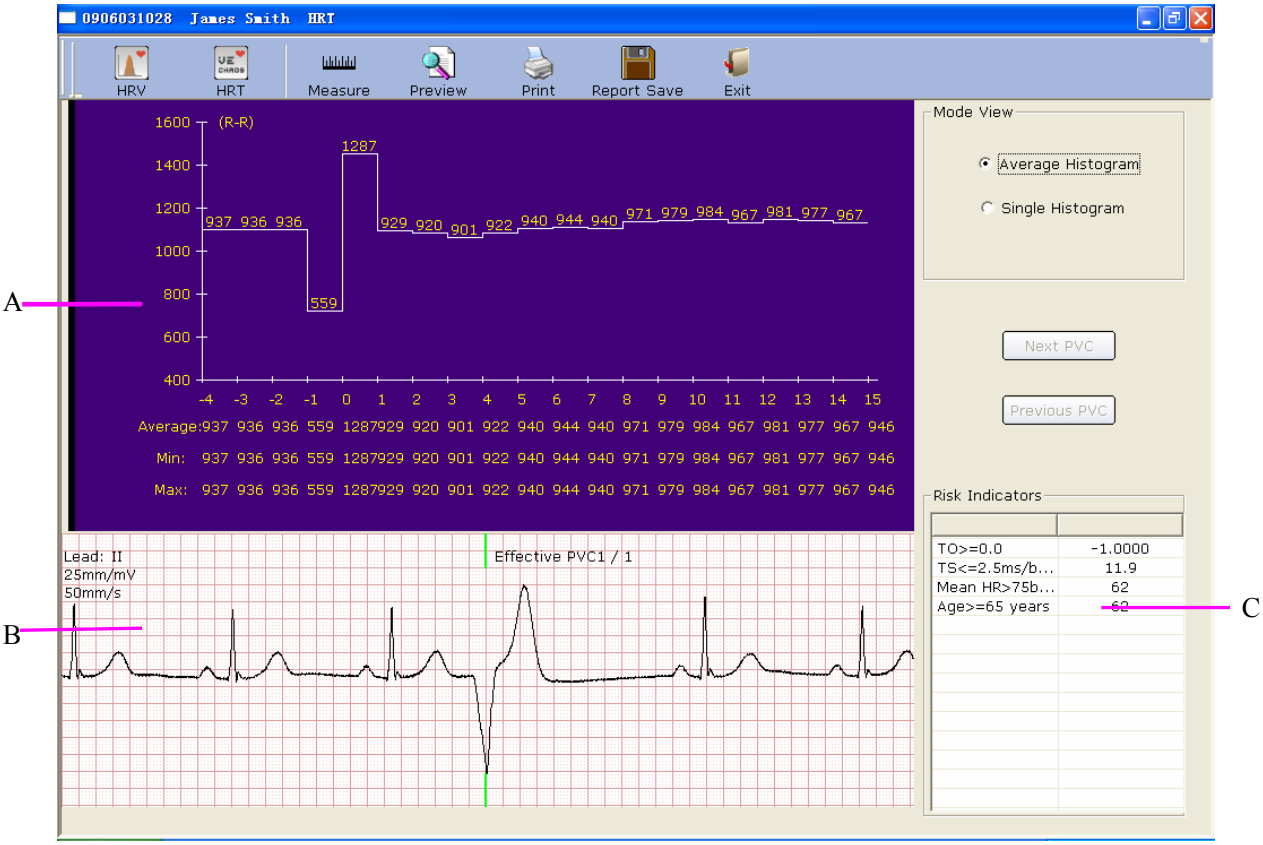


Figure 6-23 HRT Analysis Interface

A- HRT Tachogram

B- Individual PVC

C- Risk Factors

You can select **Average Histogram** or **Single Histogram**.

Click on **Previous PVC** to view the previous PVC.

Click on **Next PVC** to view the next PVC.

Click on the **Preview** button to open the HRT preview interface.

is the toolbar on the HRT preview interface.

1. Click on the **Zoom In** button on the toolbar to magnify the preview page.
2. Click on the **Zoom Out** button on the toolbar to minify the preview page.
3. Click on the **Close** button to close the HRT preview interface and return to the previous interface.

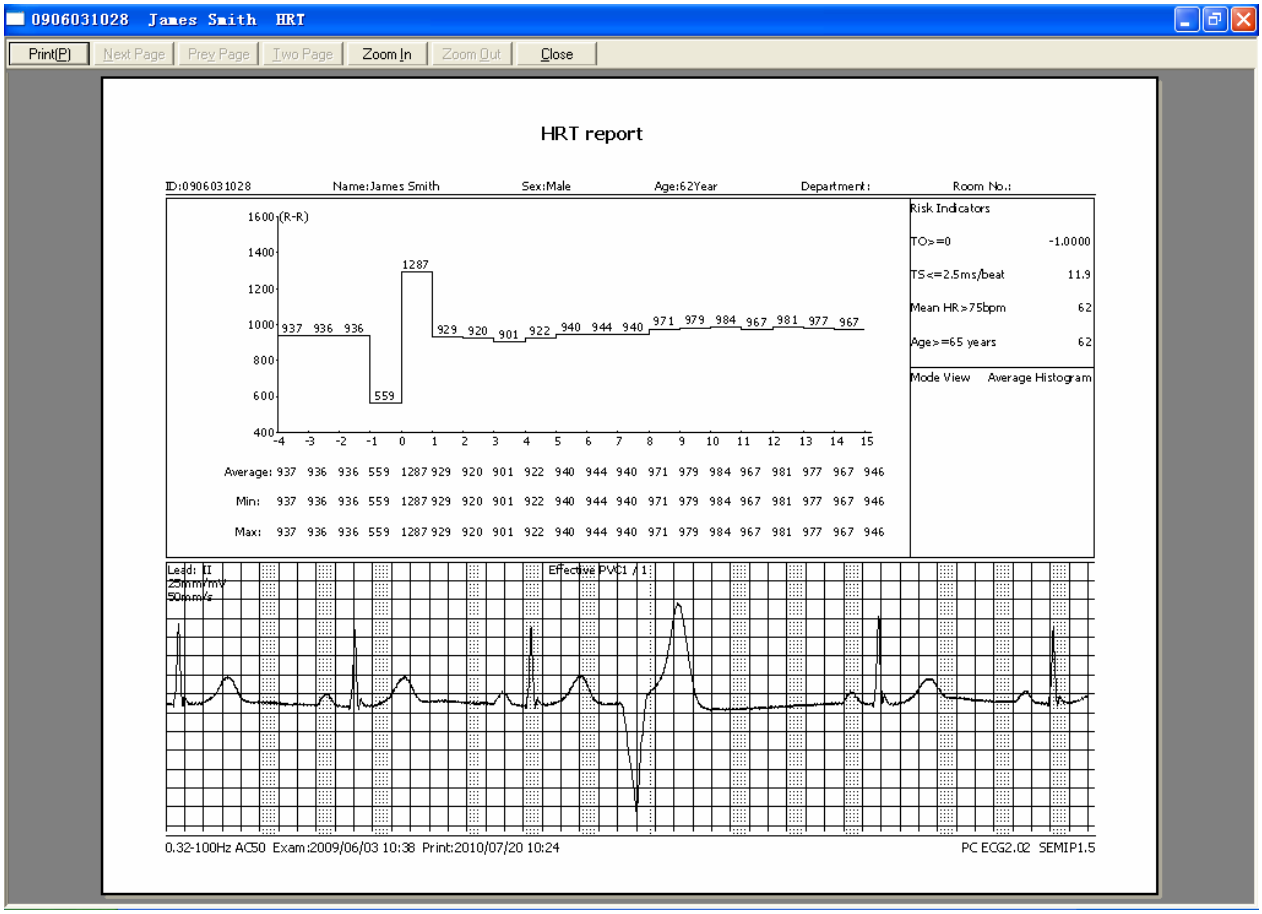
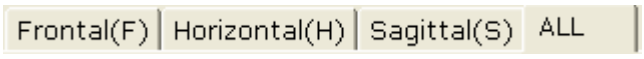


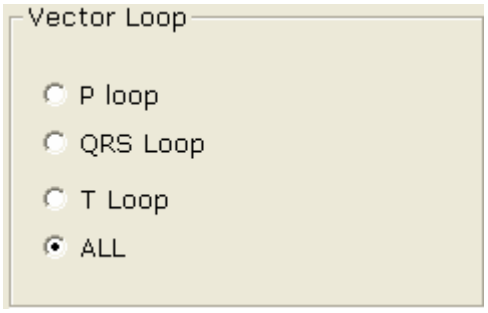
Figure 6-24 HRT Preview Interface

6.6.7 Analyzing Vector ECG

Click on the **VCG** button on the ECG analysis interface to display the VCG analysis interface. Vector ECG displays 3D image of ECG activity.

You can choose the plane 

and the vector loop



on the VCG analysis interface. Plane choices include **Frontal (F)**, **Horizontal (H)**, **Sagittal(S)** and **ALL**. Loop choices include **P loop**, **QRS loop**, **T loop** and **ALL**.

6.6.7.1 Displaying Vector ECG with All Plane and All Loop

Set the plane to **ALL** and the loop to **ALL**.

Figure 6-25 displays Vector ECG with the plane of **ALL** and the loop of **ALL**.

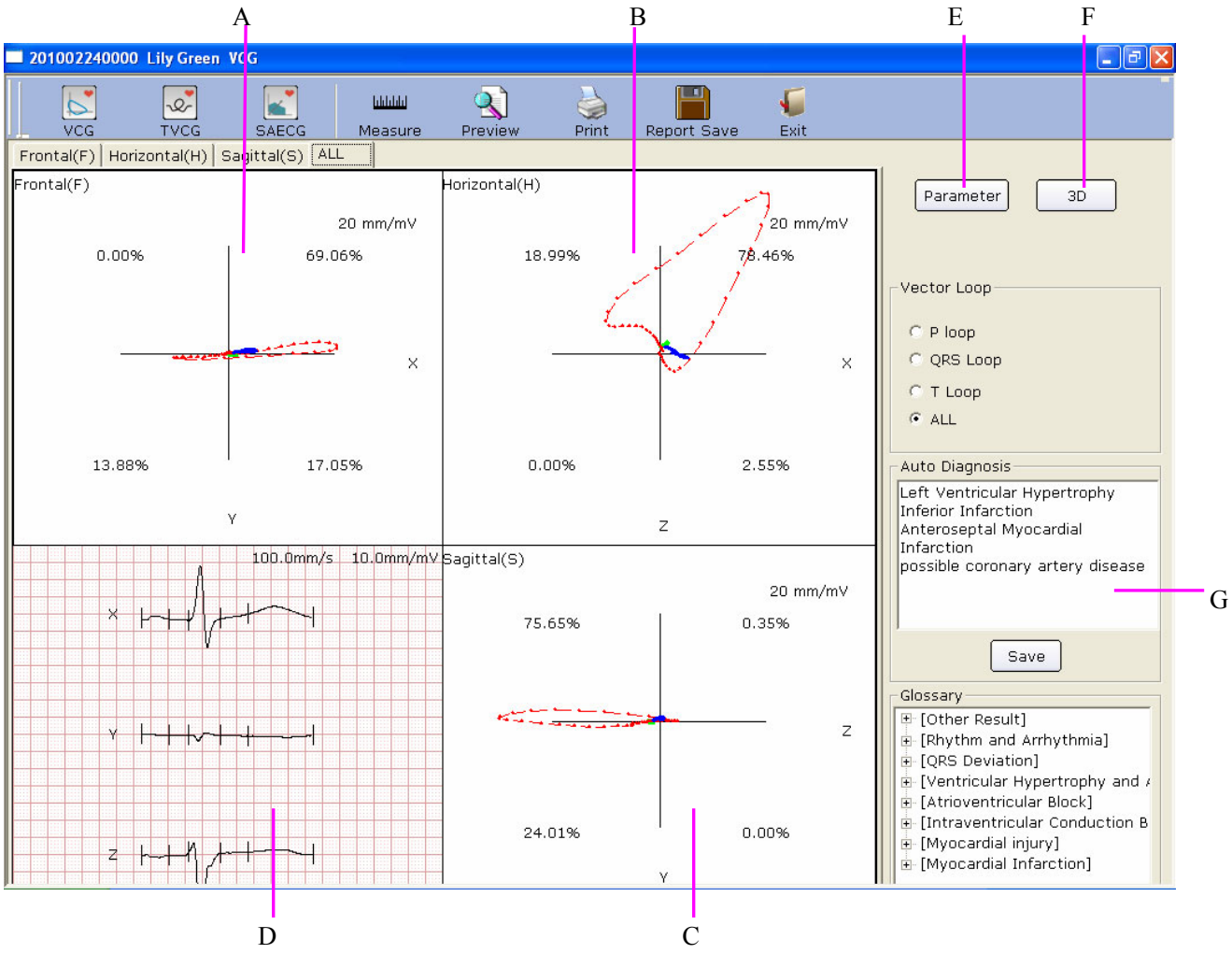


Figure 6-25 Vector ECG - Plane of ALL and Loop of ALL

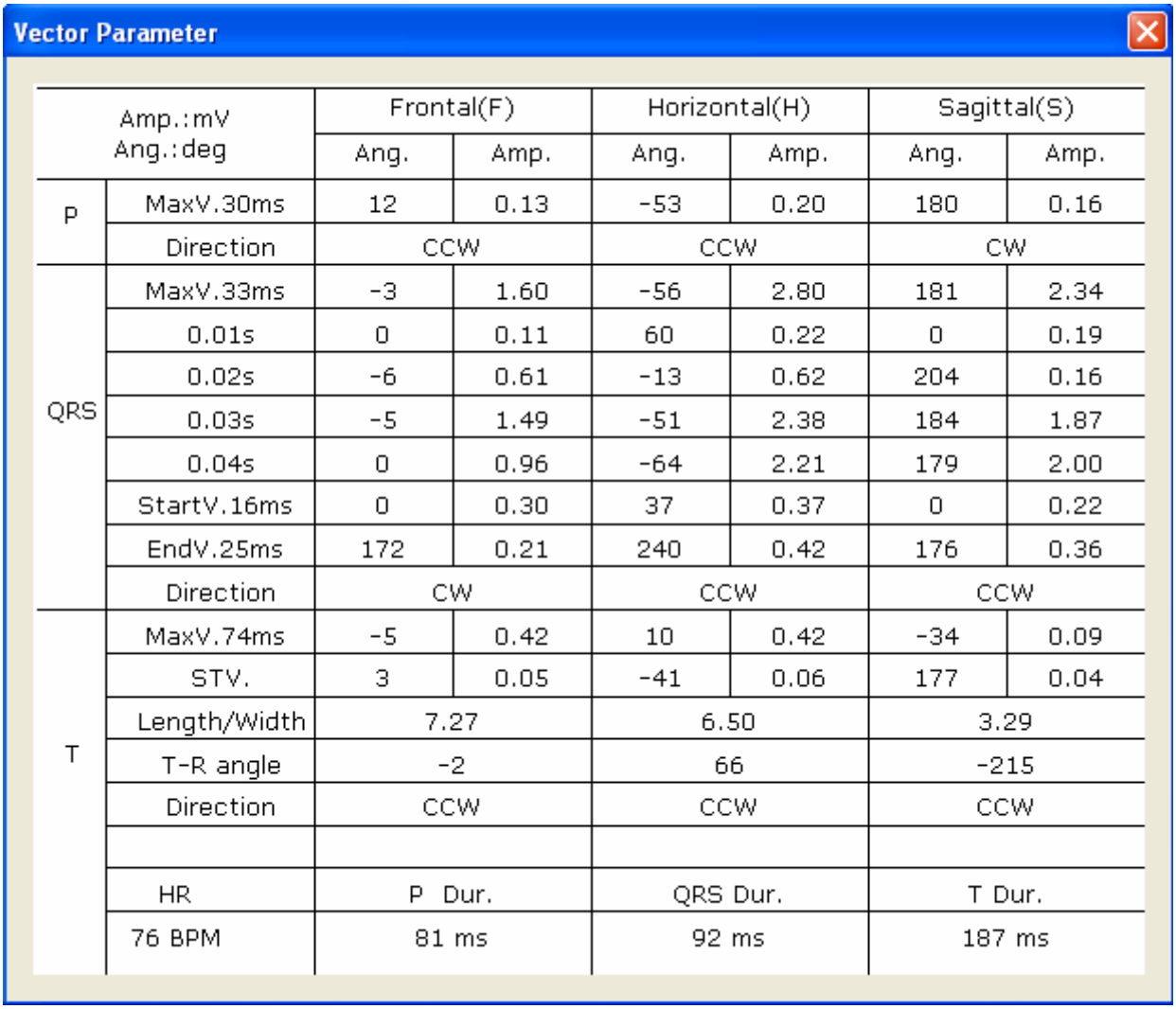
A- Vector ECG of Frontal (F)

B- Vector ECG of Horizontal (H)

C- Vector ECG of Sagittal (S)

D- Average templates of X, Y and Z leads. Double-click on this figure to display the magnified average template. You can drag these lines marked P1, P2, Q, S, T1 and T2 on the wave. With the change of the line position, the corresponding parameter values change.

E- Click on the **Parameter** button to display the following Vector ECG parameter list.



Vector Parameter

Amp.:mV Ang.:deg		Frontal(F)		Horizontal(H)		Sagittal(S)	
		Ang.	Amp.	Ang.	Amp.	Ang.	Amp.
P	MaxV.30ms	12	0.13	-53	0.20	180	0.16
	Direction	CCW		CCW		CW	
QRS	MaxV.33ms	-3	1.60	-56	2.80	181	2.34
	0.01s	0	0.11	60	0.22	0	0.19
	0.02s	-6	0.61	-13	0.62	204	0.16
	0.03s	-5	1.49	-51	2.38	184	1.87
	0.04s	0	0.96	-64	2.21	179	2.00
	StartV.16ms	0	0.30	37	0.37	0	0.22
	EndV.25ms	172	0.21	240	0.42	176	0.36
	Direction	CW		CCW		CCW	
T	MaxV.74ms	-5	0.42	10	0.42	-34	0.09
	STV.	3	0.05	-41	0.06	177	0.04
	Length/Width	7.27		6.50		3.29	
	T-R angle	-2		66		-215	
	Direction	CCW		CCW		CCW	
	HR	P Dur.		QRS Dur.		T Dur.	
	76 BPM	81 ms		92 ms		187 ms	

Designation	**Definition**
Max Vector	The position of the maximal amplitude of QRS/P/T loop (mV)
Amplitude	The amplitude of the Max vector of QRS/P/T loop (mV)
Angle	The angle of the Max vector of QRS/P/T loop (degree)
Direction	Rotation direction of QRS/P/T loop
CW	Clockwise
CCW	Counter-clockwise
8	‘8’ font ring
0.01 (amplitude)	The amplitude at 0.01s from QRS loop
0.01 (angle)	The angle at 0.01s from QRS loop
0.02 (amplitude)	The amplitude at 0.02s from QRS loop
0.02 (angle)	The angle at 0.02s from QRS loop
0.03 (amplitude)	The amplitude at 0.03s from QRS loop
0.03 (angle)	The angle at 0.03s from QRS loop

0.04 (amplitude)	The amplitude at 0.04s from QRS loop
0.04 (angle)	The angle at 0.04s from QRS loop
Start Vector	Start point of QRS loop
End Vector	End point of QRS loop
ST Vector	The position of ST vector in vector loop
Length/Width	The ratio of length to width in T loop
T-R angle	The degree between the Max vector of T loop and the Max vector of QRS loop (degree)

F- Click on **3D** to display the 3D VCG graph.

G- Diagnosis Field

1. Enter your own opinions in the **Auto Diagnosis** textbox, and then click on the **Save** button.

2. Or double-click on the necessary results required to be added in the **Glossary** textbox, and the selected results will be displayed in the **Auto Diagnosis** textbox, and then click on the **Save** button.

6.6.7.2 Displaying Vector ECG with Frontal Plane and QRS Loop

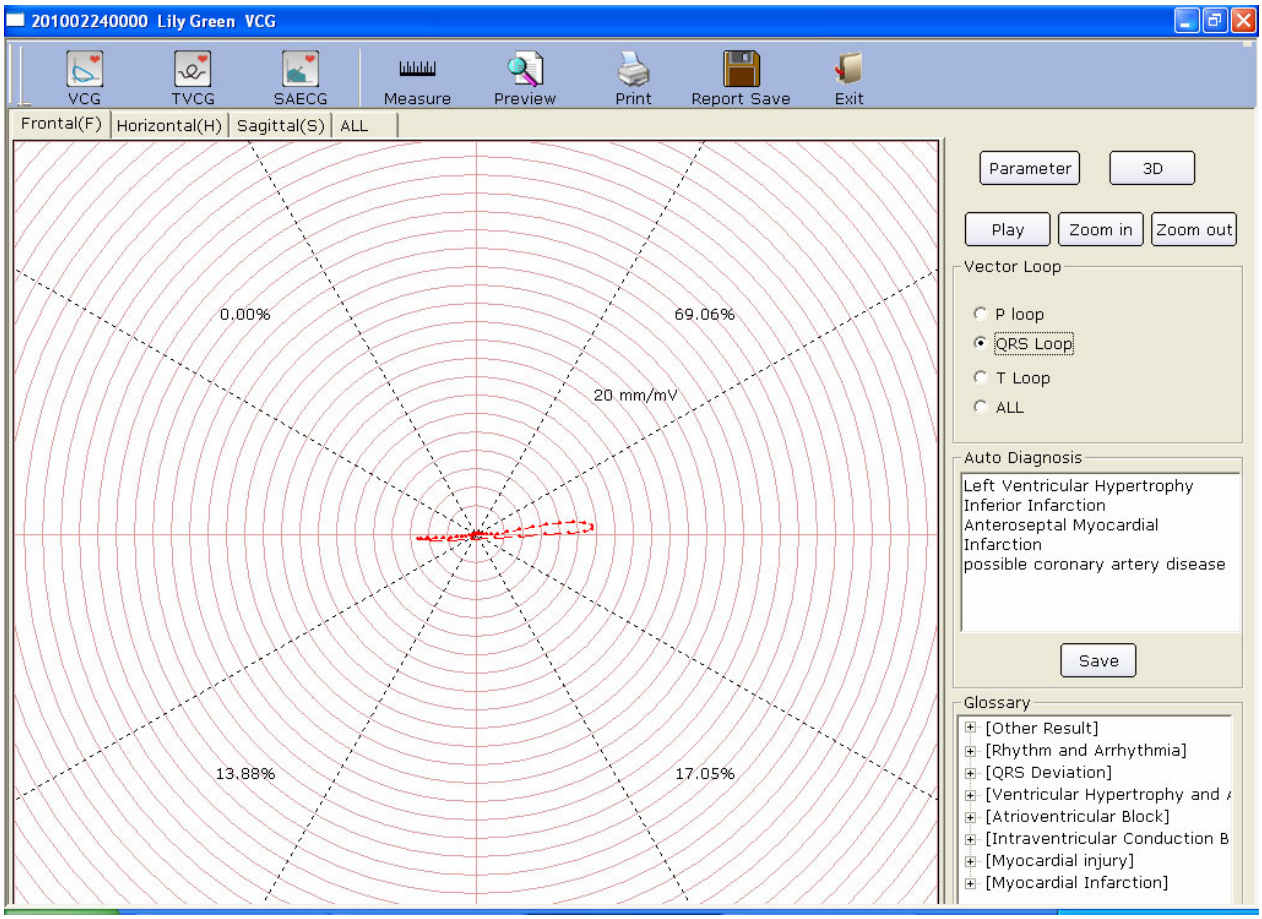


Figure 6-26 Vector ECG - Frontal & QRS loop

The percent values of **0.00%**, **69.06%**, **13.88%** and **17.05%** in the square represent the area

percentages of QRS loop in every quadrant. **20 mm/mV** indicates the magnified multiple (gain). The red curve is QRS loop.

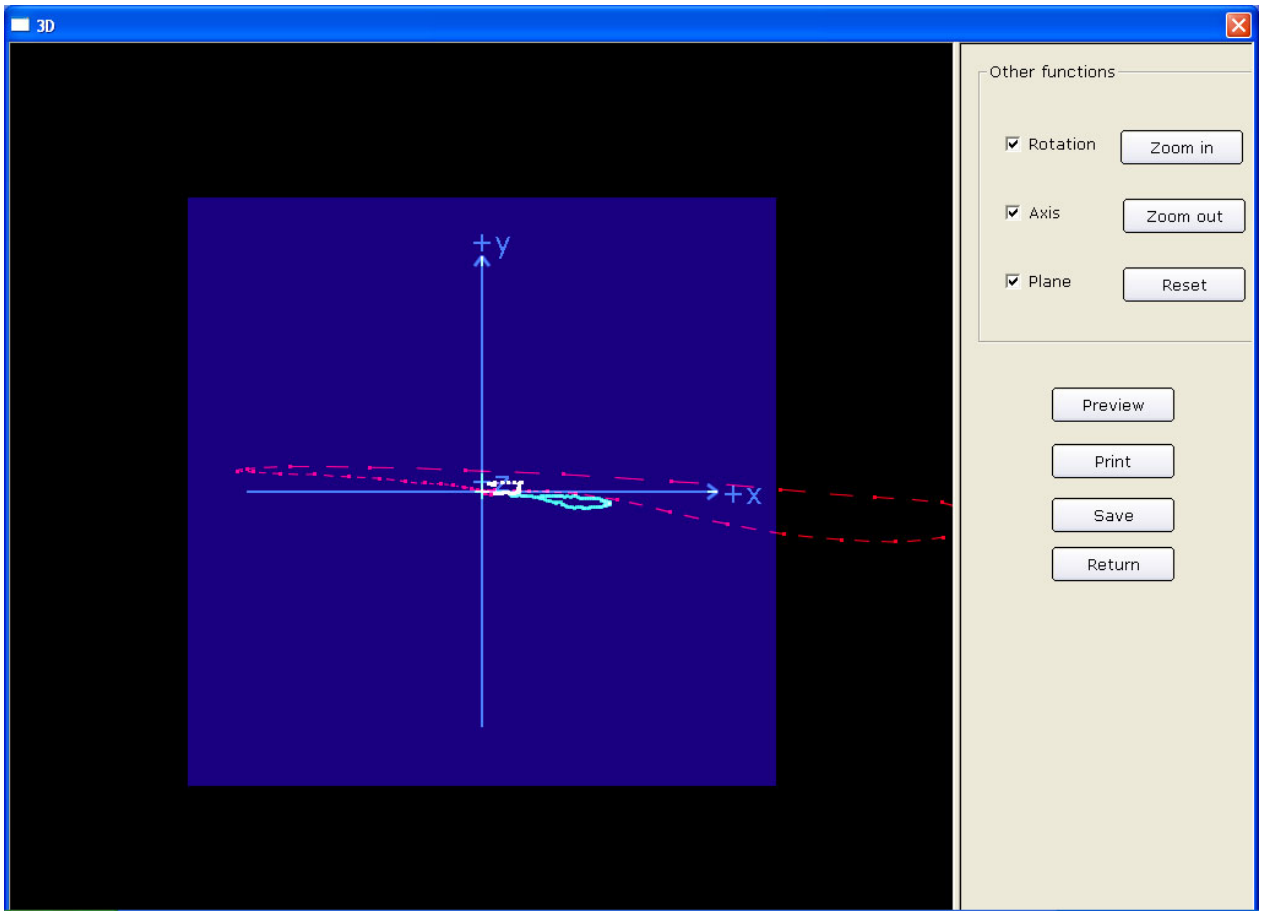
You can click on the **Zoom in** button or the **Zoom out** button to change the gain of the displayed graphics. You can click on the **Play** button to watch the forming process of the QRS loop.

6.6.7.3 Displaying 3D Vector ECG

Click on **3D** to display the 3D VCG graph.

3D (Three Dimensional Vector Loops)

This function allows you to observe the Vector ECG in three dimensions. Check **Rotation**, and then you can rotate the whole picture to see all directions of the vector loops. Check **Axis** to display the axes. Check **Plane** to display the planes.



Click on **Save** to save the graph on the current screen.

Click on **Preview** to preview the 3D graph.

Click on **Print** to print the 3D graph.

Click on **Return** to return to the ECG analysis interface.

6.6.7.4 Previewing Vector ECG

Click on the **Preview** button to open the VCG preview interface.

is the toolbar on the VCG preview interface.

1. Click on the **Zoom In** button on the toolbar to magnify the preview page.
2. Click on the **Zoom Out** button on the toolbar to minify the preview page.
3. Click on the **Close** button to close the VCG preview interface and return to the previous interface.

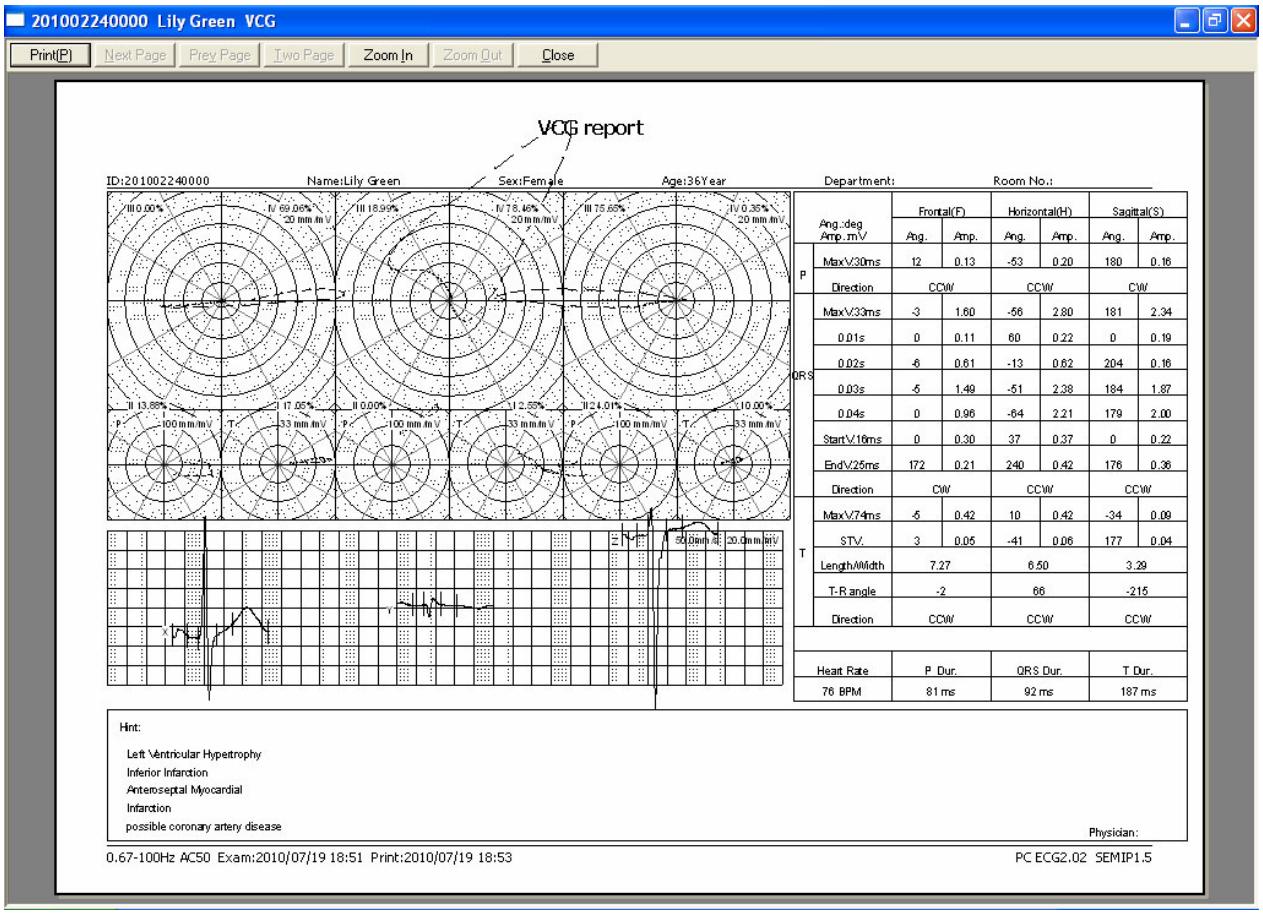


Figure 6-27 VCG Preview Interface (Plane is ALL & loop is ALL)

6.6.8 Analyzing Time Vector ECG

Click on the **TVCG** button on the ECG analysis interface to display the TVCG analysis interface. Time Vector ECG is Vector ECG including time factor.

As Figure 6-28 shows, you can observe waves of X lead, Y lead, Z lead, X-Y lead, X-Z lead and Z-Y lead.

You can choose the speed and the gain of the displayed waves.

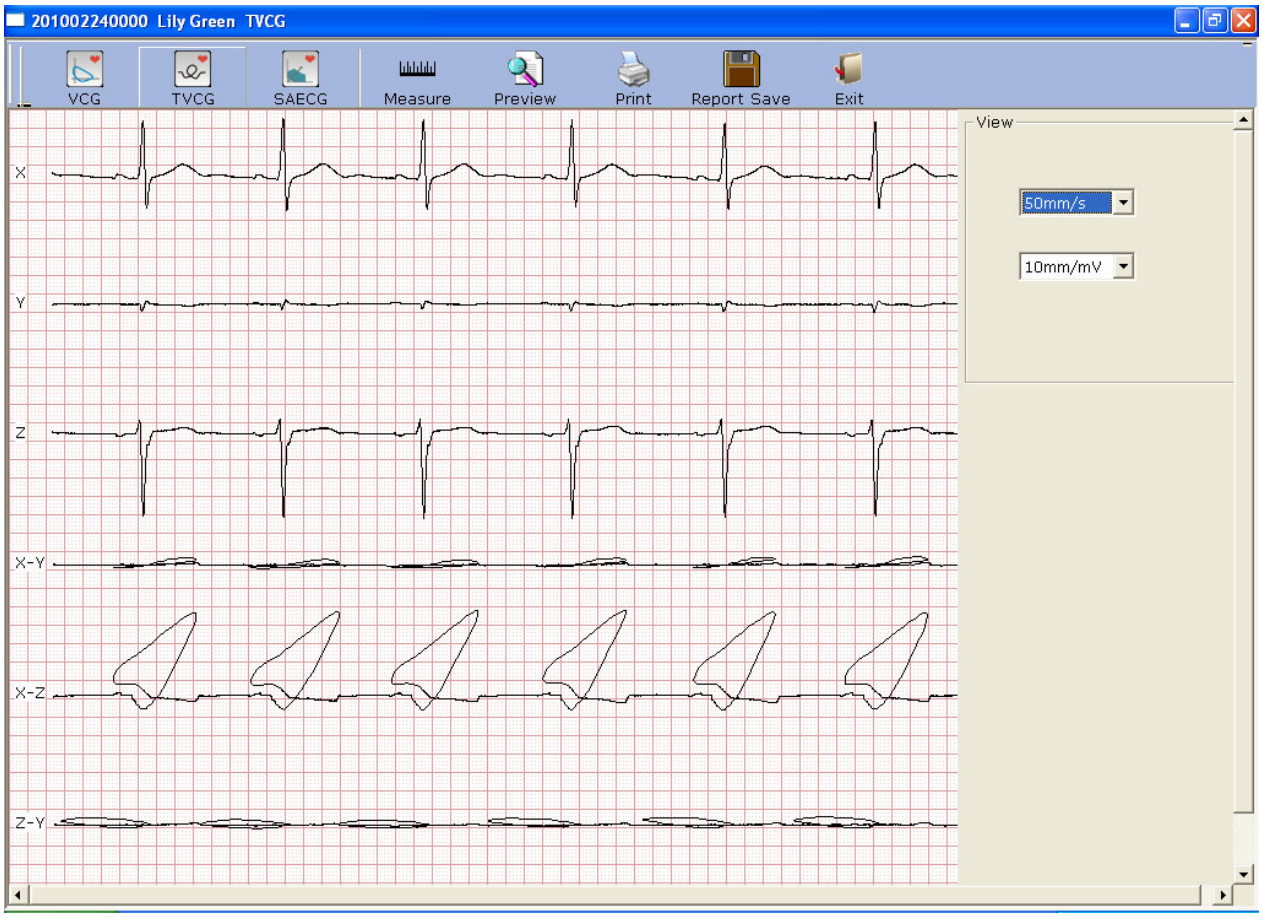


Figure 6-28 Time Vector ECG Interface

Click on the **Preview** button to display the TVCG preview interface.

is the toolbar on the TVCG preview interface.

1. Click on the **Zoom In** button on the toolbar to magnify the preview page.
2. Click on the **Zoom Out** button on the toolbar to minify the preview page.
3. Click on the **Close** button to close the TVCG preview interface and return to the previous interface.

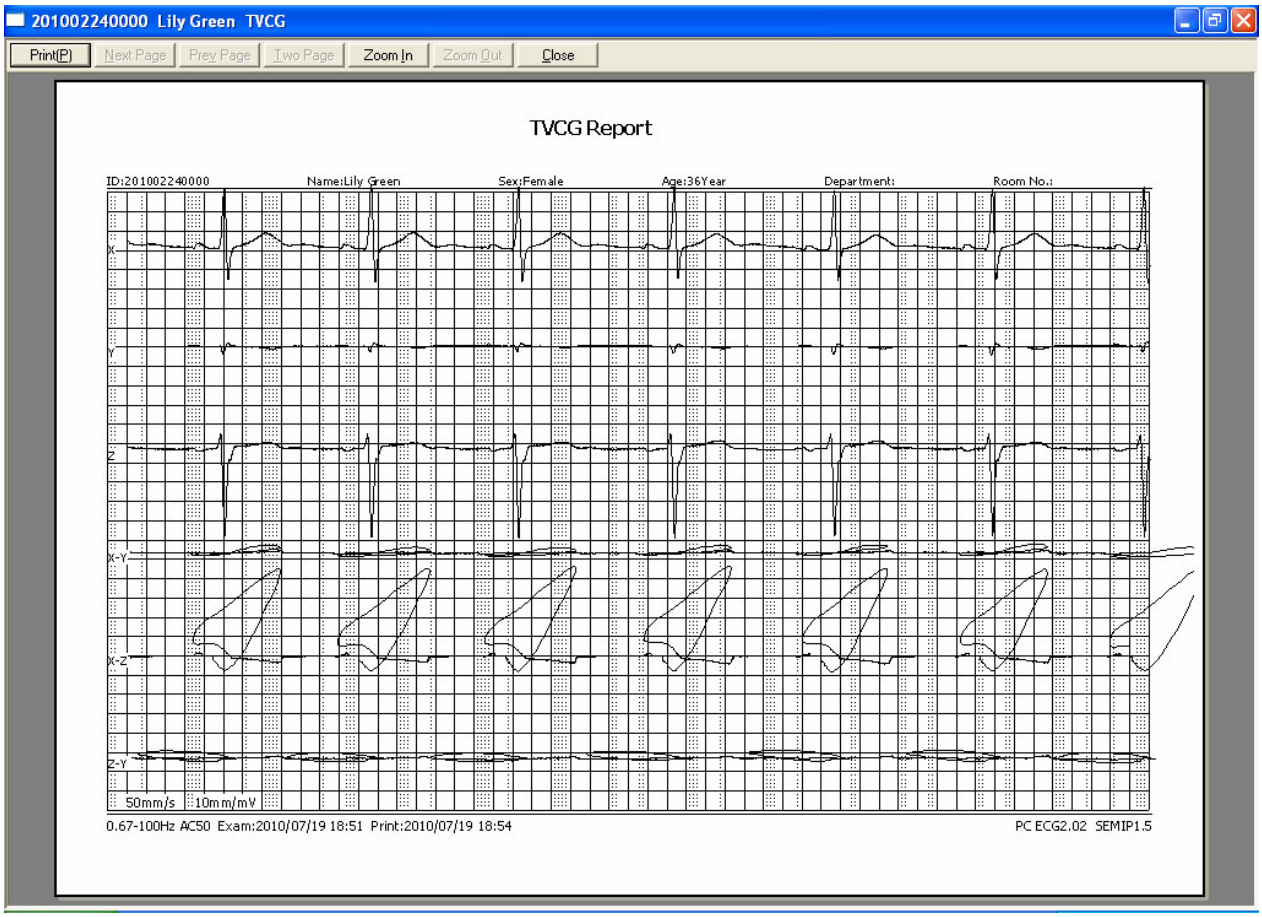


Figure 6-29 Time Vector ECG Preview Interface

6.6.9 Analyzing Signal Averaged ECG

SAECG is also called Ventricular Late Potential (VLP). Click on **SAECG** to open the SAECG analysis interface. The SAECG analysis interface includes two tabs: **Time domain** and **Frequency domain**.

6.6.9.1 About the Time Domain Interface

Click on the **Time domain** tab to open the time domain interface.

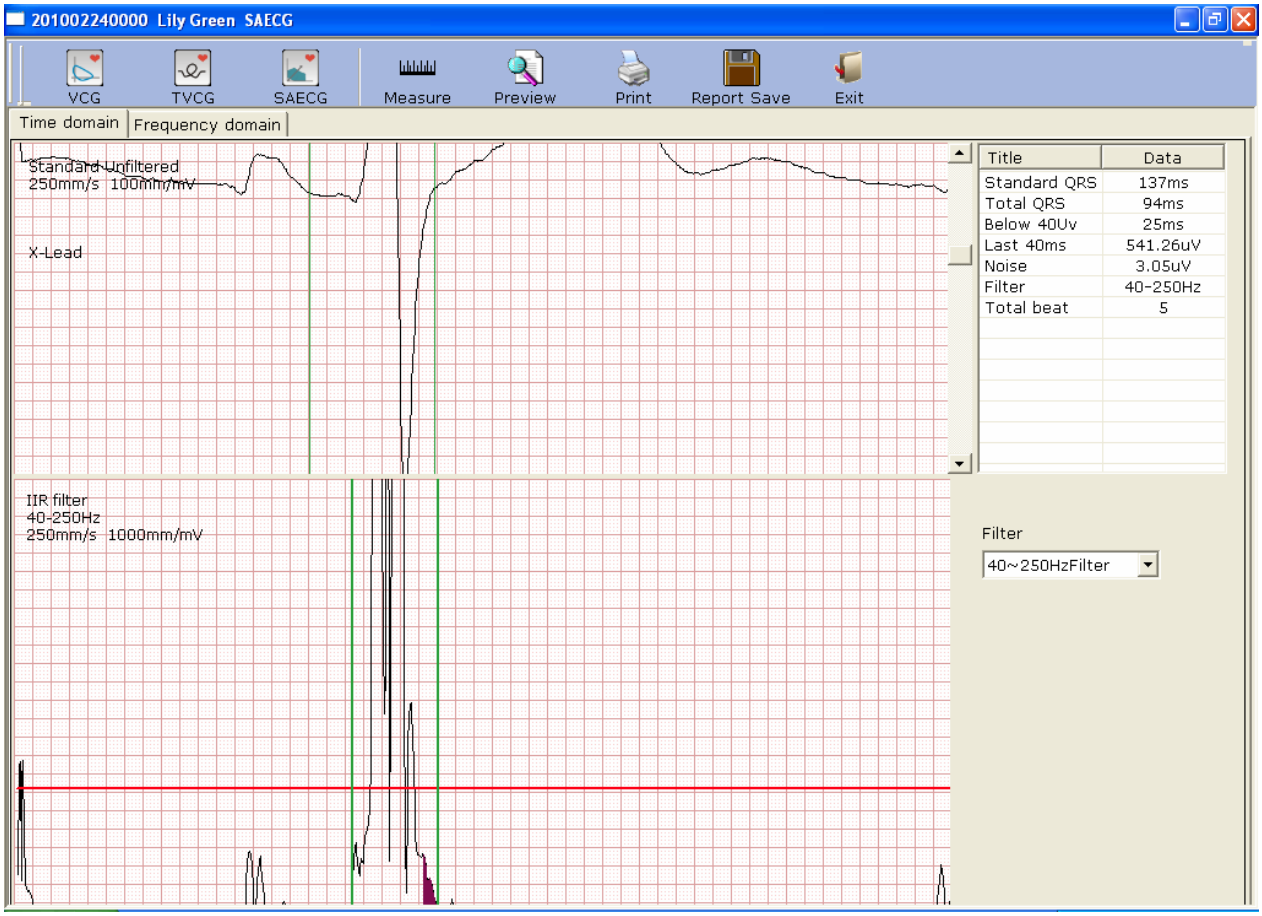
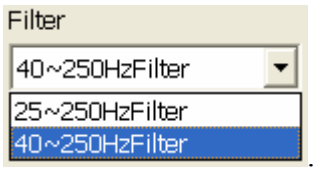


Figure 6-30 Time Domain Interface

There are four vertical lines and one horizontal fixed measurement line on this interface.

You can drag the green vertical lines on the ECG wave, and then the corresponding parameters in the right part will change.

Select a filter in the **Filter** pull-down list 

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6.6.9.2 About the Frequency Domain Interface

Click on the **Frequency domain** tab to open the frequency domain interface.

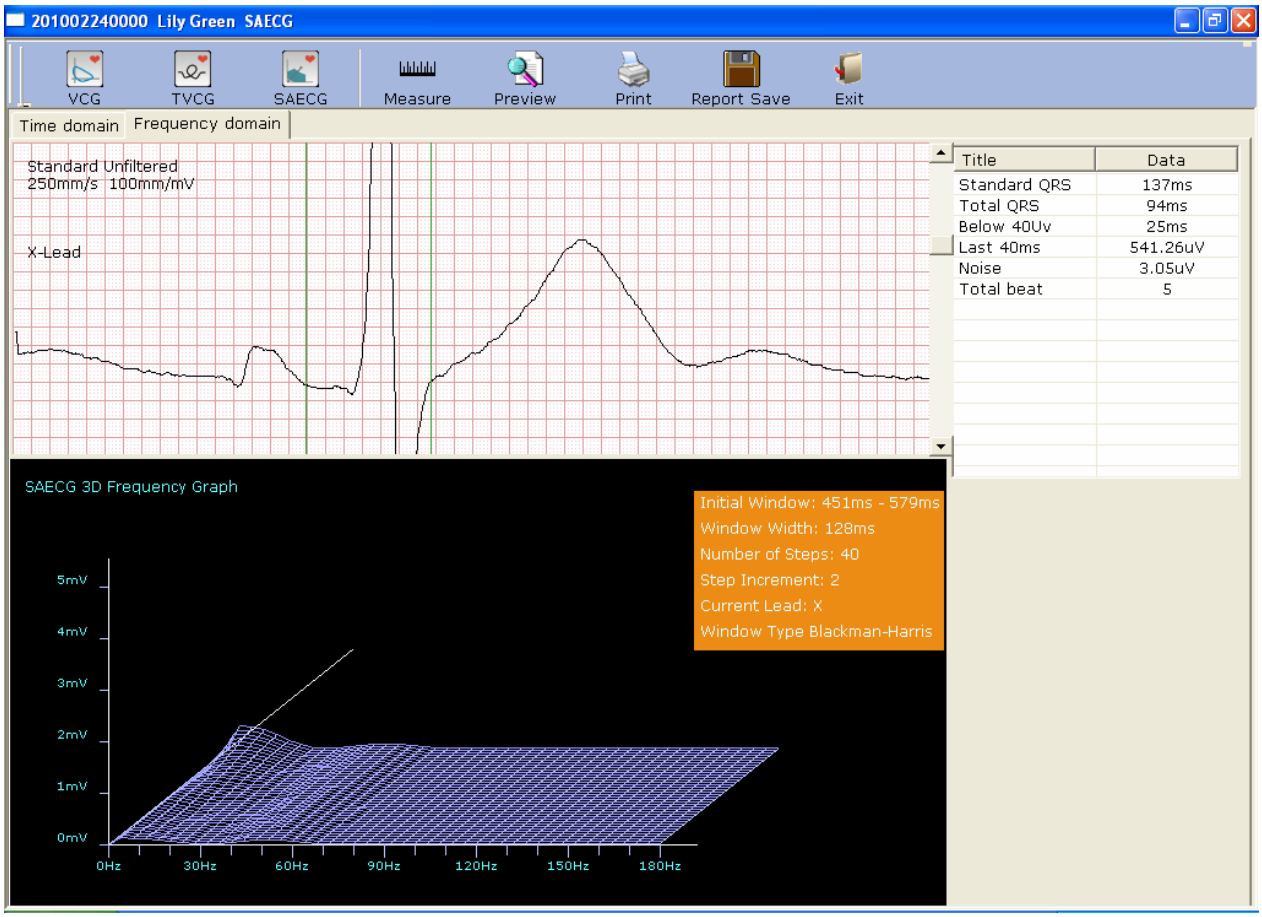


Figure 6-31 Frequency Domain Interface

You can drag the green vertical lines on the ECG wave, and the corresponding parameters in the right part and the 3D graph in the bottom part will change.

6.6.9.3 Previewing Signal Averaged ECG

Click on the **Preview** button to display the SAECG preview interface.

is the toolbar on the SAECG preview interface.

1. Click on the **Zoom In** button on the toolbar to magnify the preview page.
2. Click on the **Zoom Out** button on the toolbar to minify the preview page.
3. Click on the **Close** button to close the SAECG preview interface and return to the previous interface.

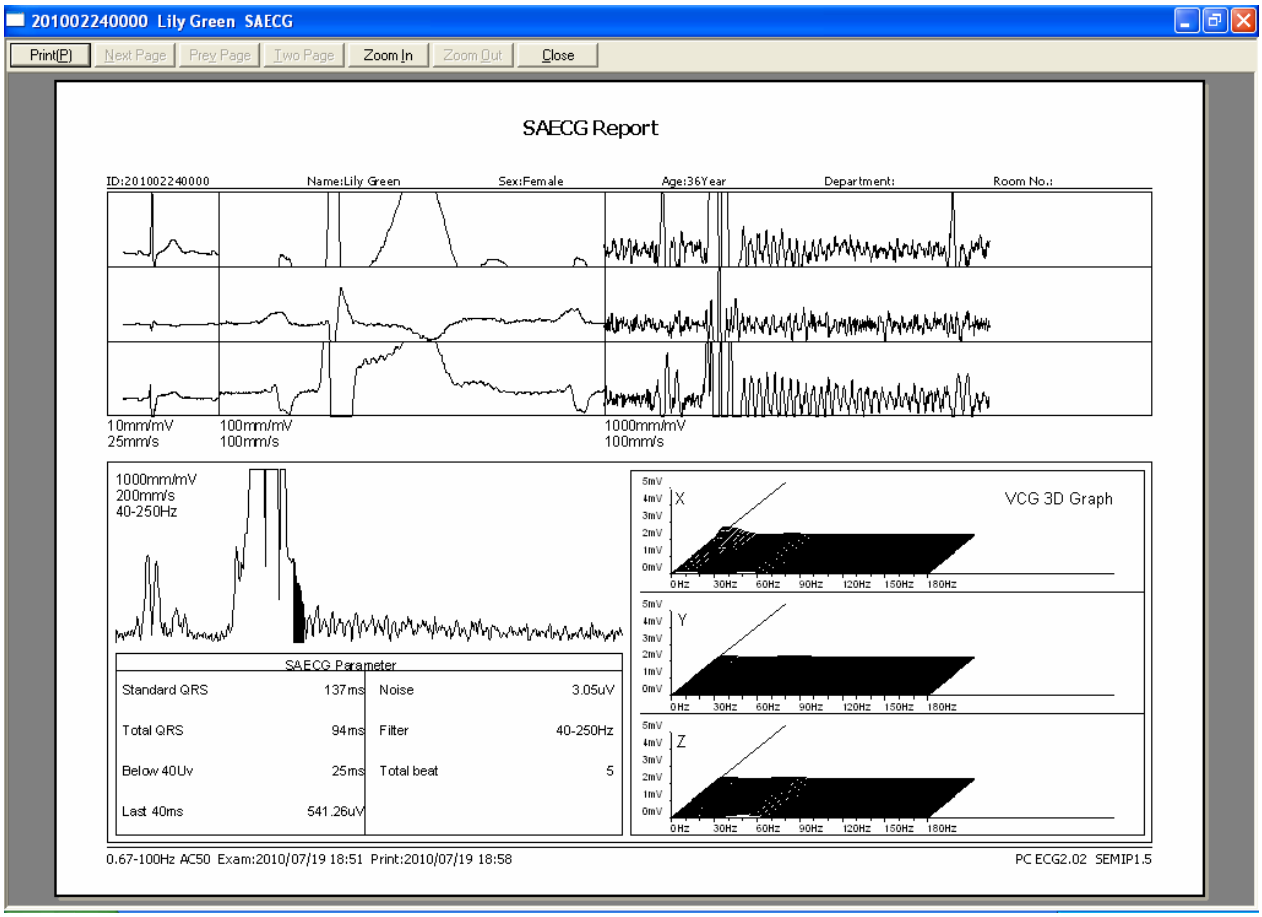
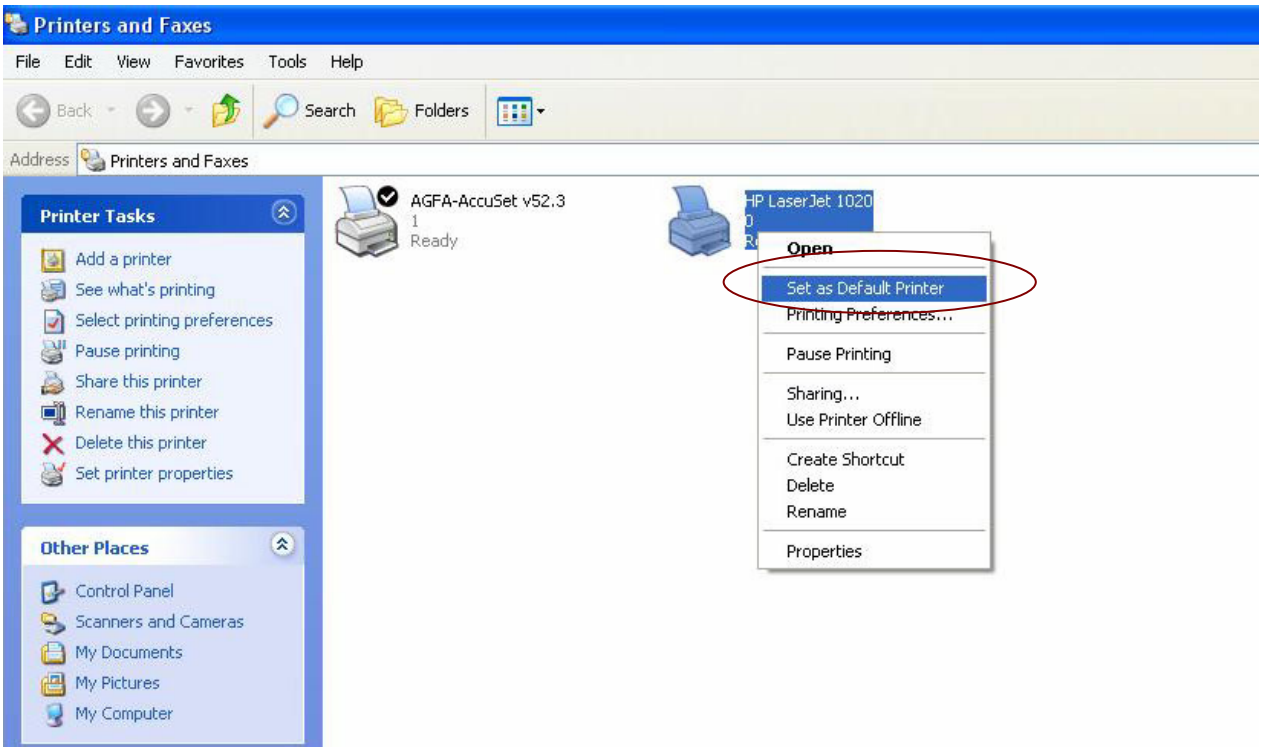


Figure 6-32 Signal Averaged ECG Report

6.6.10 Printing ECG Reports

1. Choose **Start** > **Printers and Faxes**, and then right-click on the icon of the printer used, and select **Set as Default Printer**. Then close the **Printers and Faxes** interface.



2. Click on the **Print** button on the analysis interface to print an ECG report.

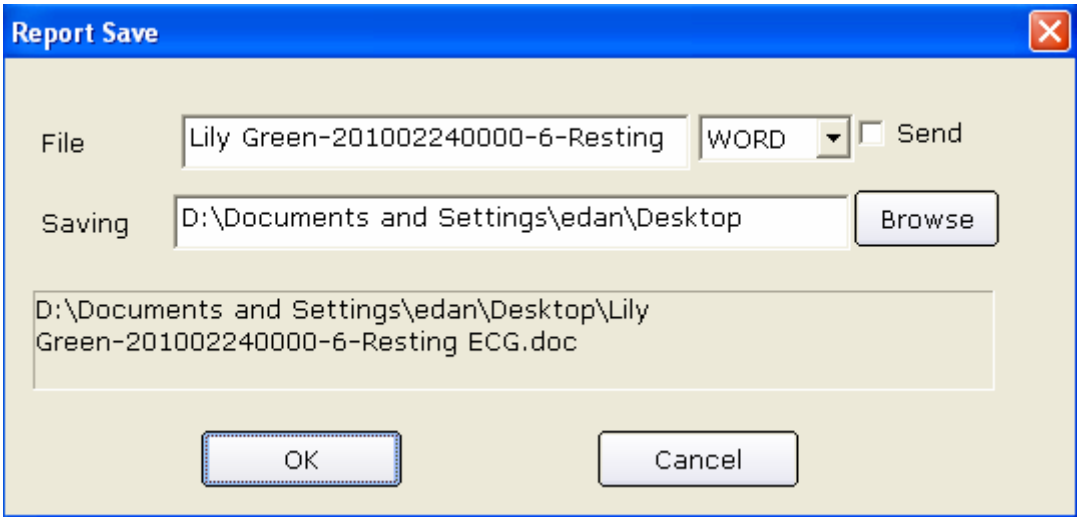
3. Or click on the **Print** button on the preview interface to print an ECG report.

6.6.11 Saving ECG Reports

You can click on the **Report Save** button

to save ECG reports.

The report format includes **PDF**, **WORD**, **JPG** and **BMP**. Click on the **Browse** button to choose the save path and click on **OK** to save the sampled data to the designated directory. During the saving course, the system will give the hint information.



If you select **Send**, the sampled data will be sent by email (outlook express) when it is saved to the designated directory. During the saving and sending course, the system will give the hint information.

Notes:

1. In Windows 7/Vista, only if OUTLOOK EXPRESS is installed, can the report be sent by email.

2. Before saving reports, you should install the Microsoft Word or PDFCreator software in the PC; otherwise Report Save can not be realized.

6.7 Sampling STAT ECG

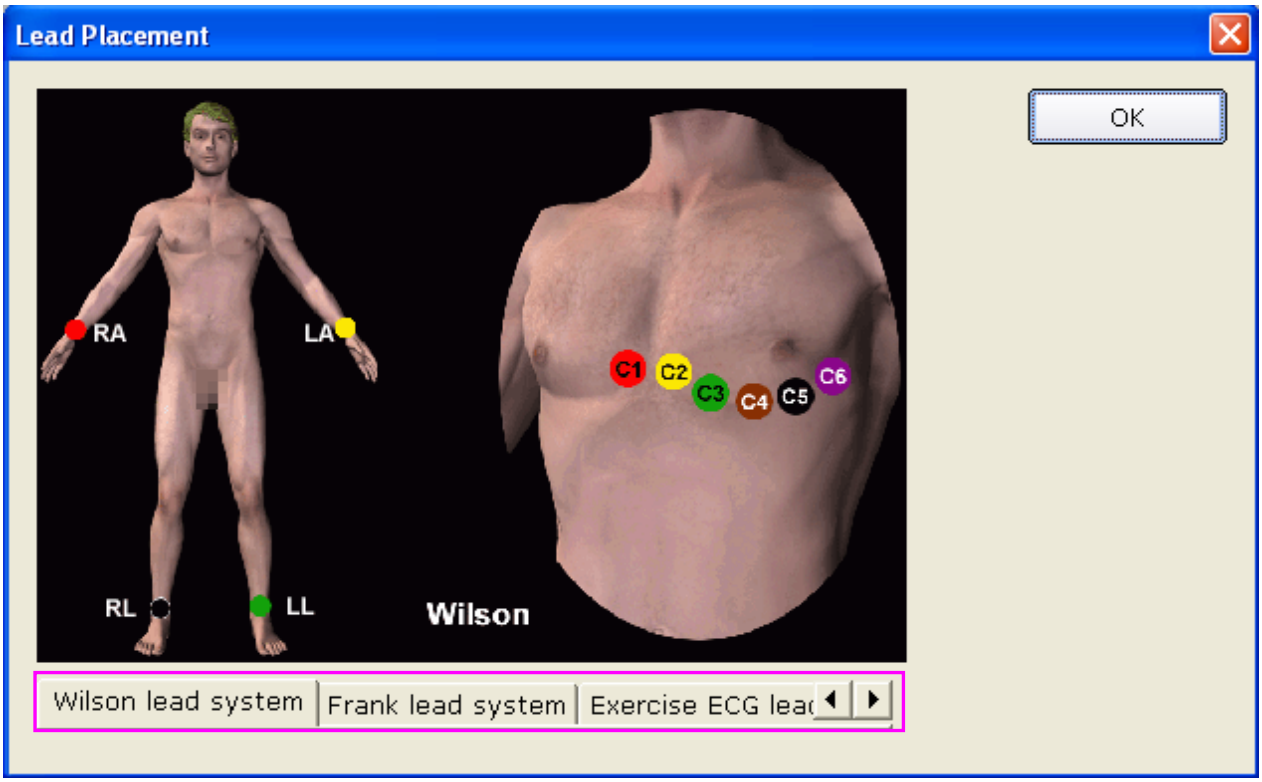
Click on the **STAT ECG** button on the initial interface (Figure 6-1) to sample normal ECG directly without entering new patient information or selecting an existing patient record from the database before sampling. The system will automatically distribute a new patient ID.

Chapter 7 Operation Instructions for Exercise ECG

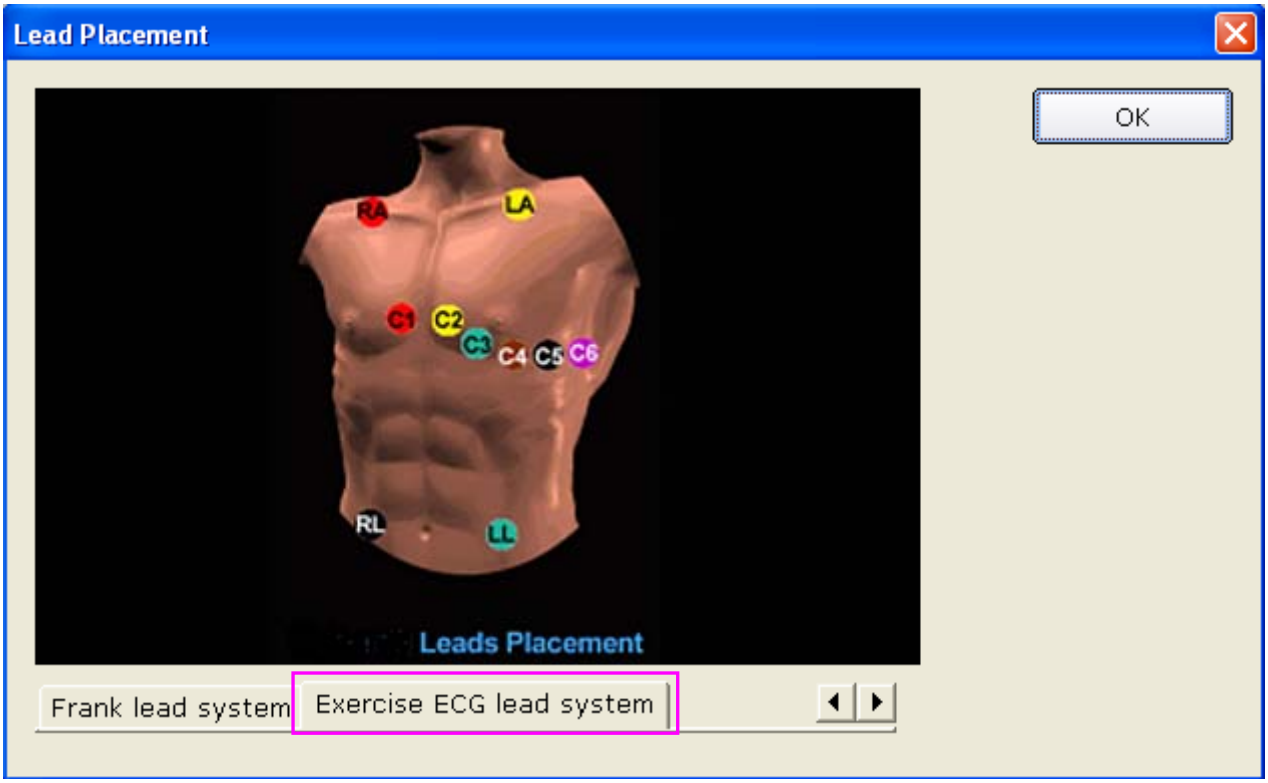
The exercise ECG function is optional. It is available only if you purchased this function.

7.1 Viewing Lead Placement Information

1. Click on the **Lead Placement** button on the initial interface to display the **Lead Placement** window.



2. Click on **Exercise ECG lead system** to view the lead placement information.

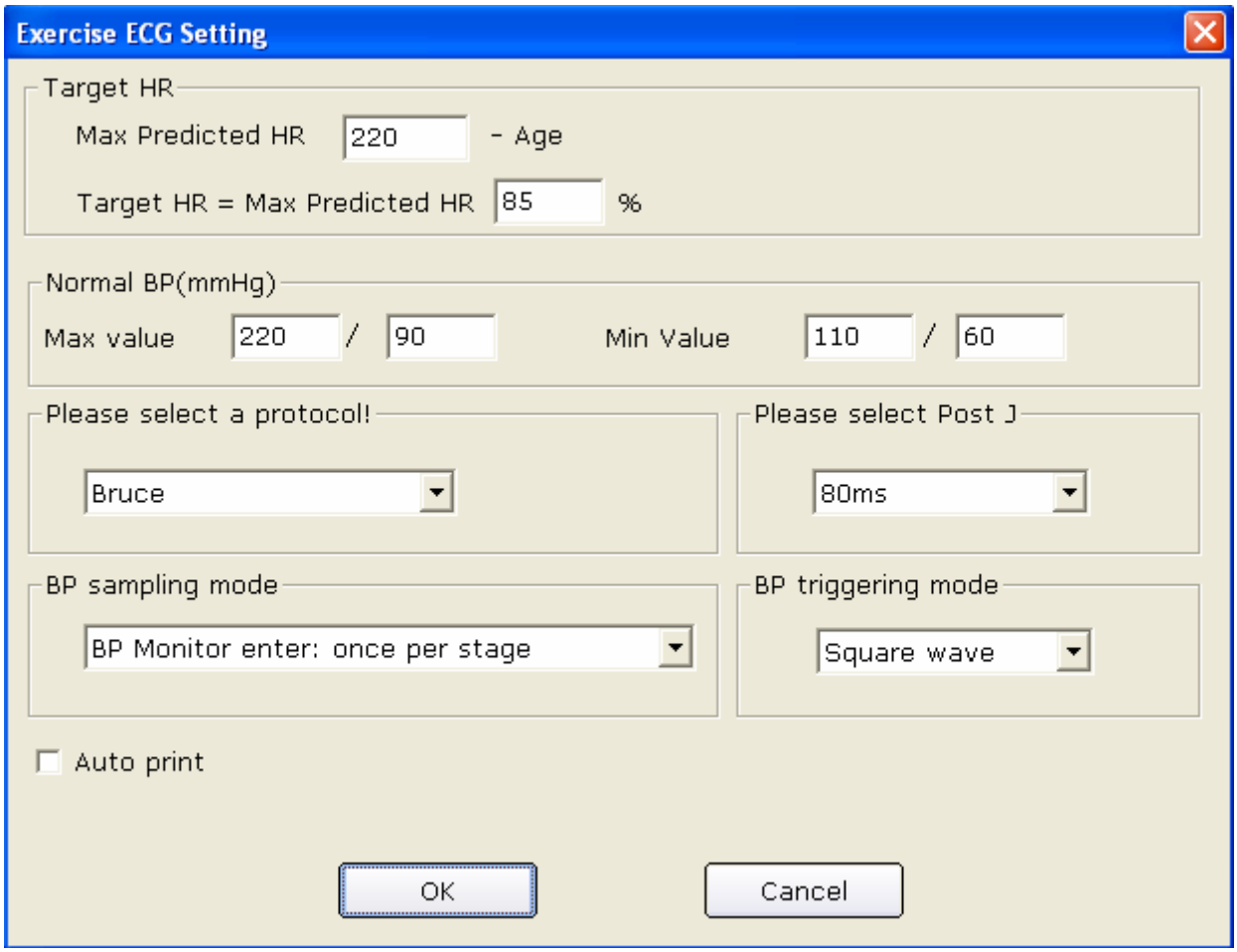


7.2 Selecting a Patient Record to Start a New Test

1. You can select a patient record from the database to start a new test. The operation steps are the same as those of resting ECG. For details, refer to Section 6.2, “Selecting a Patient Record to Start a New Test”.

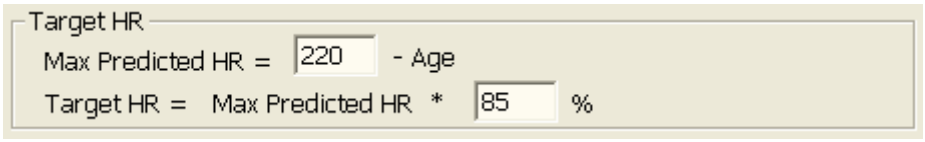
2. Select **Exercise ECG** on the **Patient information** interface.

3. Click on **OK** on the **Patient information** interface to open the **Exercise ECG Setting** interface. After setting the parameters, click on the **OK** button to open the pre-sampling interface.



7.2.1 Setting Target HR

The system applies the following formulas to calculate the target heart rate.

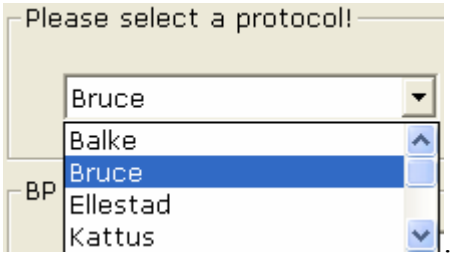


220 and **85** are default values, and you can modify them in different situations on the **Exercise ECG Setting** interface.

7.2.2 Setting Normal BP

Set the normal BP range on the **Exercise ECG Setting** interface. When the patient's BP exceeds the normal BP range, the system will consider it as abnormal status.

7.2.3 Setting a Protocol

Select a protocol from the pull-down list 

.

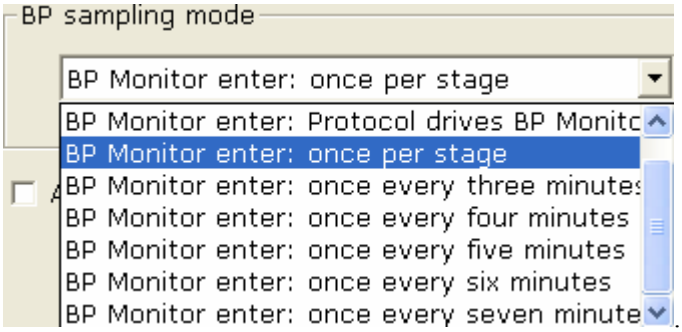
7.2.4 Setting Post J

Select a Post J value from the Post J pull-down list on the **Exercise ECG Setting** interface.

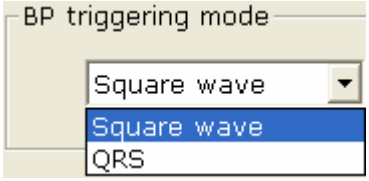
Post J is the length after J point of the ST segment. You can set Post J to **0ms**, **20ms**, **40ms**, **60ms** or **80ms**.

Note: J Point is the connection point between the end of QRS complex and the start of ST segment. It is the standard point to fix the position of ST segment in this system. Please select the proper option based on the patient's actual ECG waves.

7.2.5 Setting BP Sampling Mode

Select a BP sampling mode from the **BP sampling mode** list 
BP sampling mode
BP Monitor enter: once per stage
BP Monitor enter: Protocol drives BP Monitc
BP Monitor enter: once per stage
BP Monitor enter: once every three minutes
BP Monitor enter: once every four minutes
BP Monitor enter: once every five minutes
BP Monitor enter: once every six minutes
BP Monitor enter: once every seven minute
.

7.2.6 Setting BP Triggering Mode



You can set the BP triggering mode to **Square wave** or **QRS** on the **Exercise ECG Setting** interface.

7.2.7 Setting Auto Printing

Select **Auto print** to print ECG reports automatically.

7.3 Entering New Patient Information

If the patient is a new one,

1. Click on the **New Patient** button

on the initial interface (Figure 6-1) to display the **Patient information** interface. Then enter the patient information. The operation steps are the same as those of resting ECG. For details, refer to Section 6.3, "Entering New Patient Information".

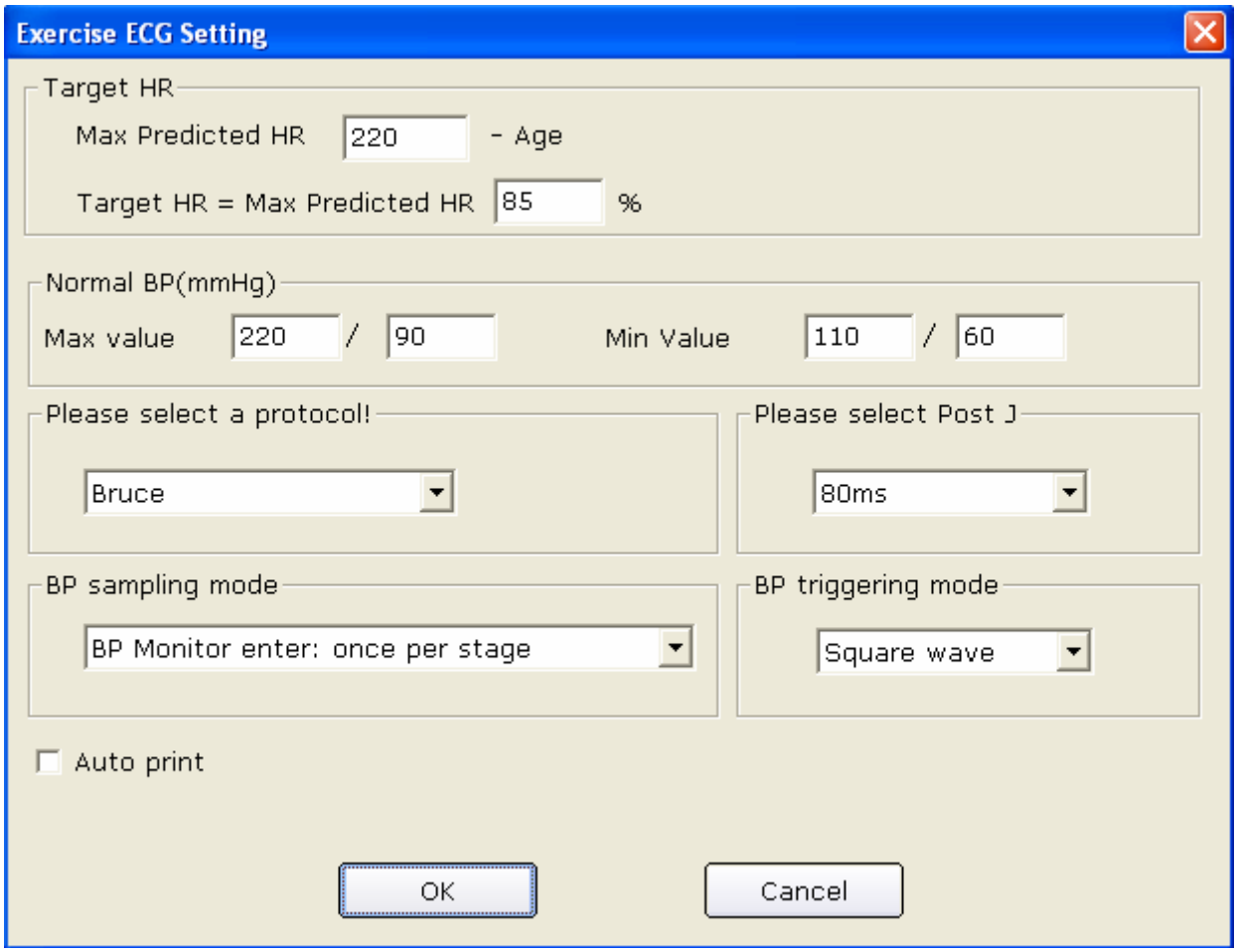
Notes:

1. Patient ID and age must be entered.

2. Please enter the correct patient age which has direct relationship with the calculation of the target heart rate.

2. Select **Exercise ECG** on the **Patient information** interface.

3. Click on **OK** on the **Patient information** interface to open the **Exercise ECG Setting** interface. After setting the parameters, click on the **OK** button to open the pre-sampling interface. For details on setting the parameters on the **Exercise ECG Setting** interface, please refer to 7.2, "Selecting a Patient Record to Start a New Test".


Exercise ECG Setting
Target HR
Max Predicted HR
220
- Age
Target HR = Max Predicted HR
85
%
Normal BP(mmHg)
Max value
220
/
90
Min Value
110
/
60
Please select a protocol!
Bruce
Please select Post J
80ms
BP sampling mode
BP Monitor enter: once per stage
BP triggering mode
Square wave
Auto print
OK
Cancel

7.4 Pre-sampling ECG

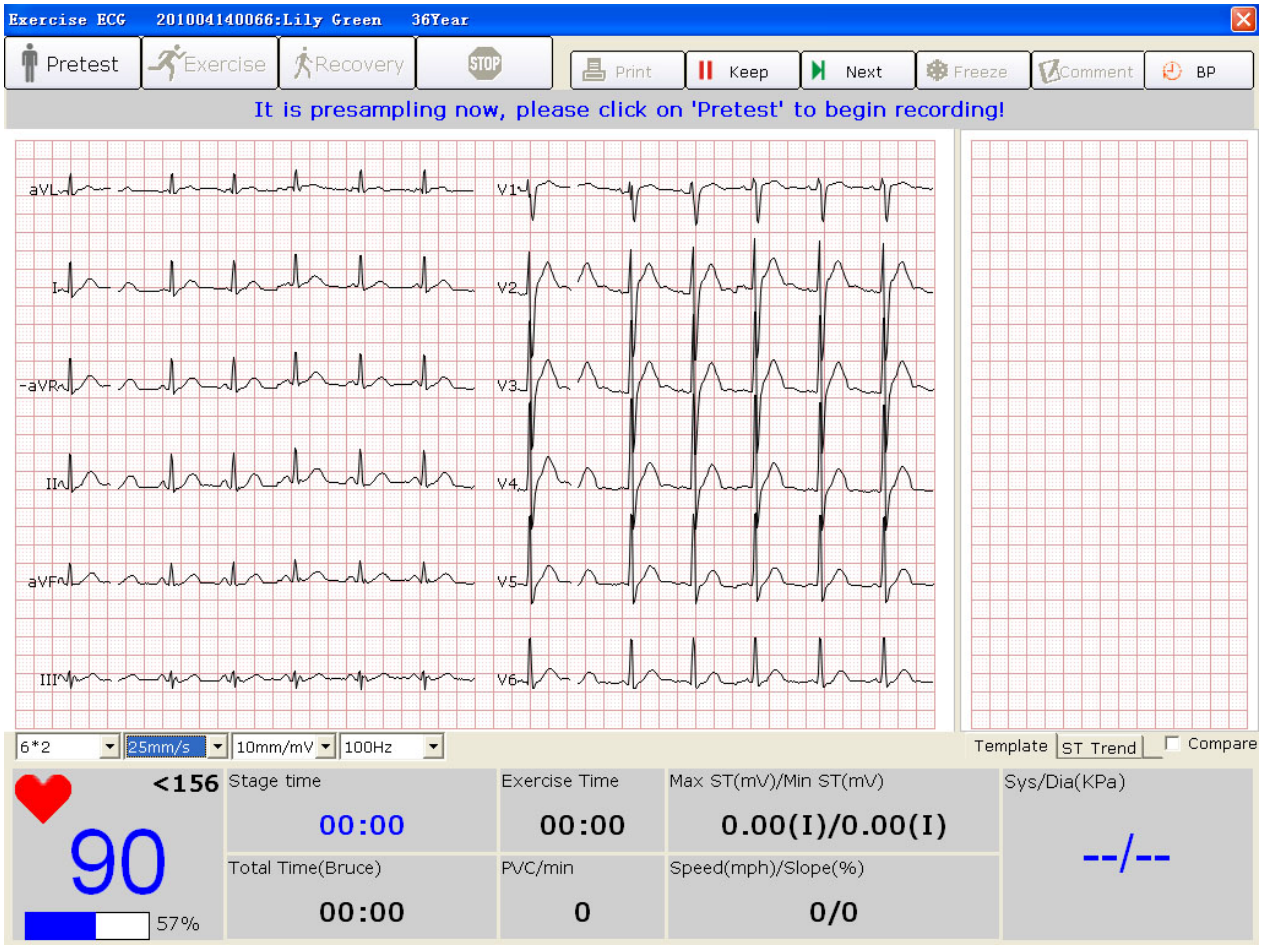
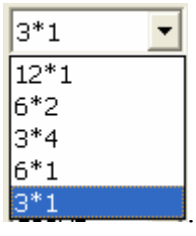


Figure 7-1 Pre-Sampling Interface

1. Select a display mode from the display mode pull-down list 

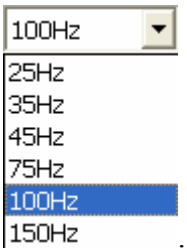
.

2. Select a gain from the gain pull-down list

.

3. Select a speed from the speed pull-down list

.

4. Select a lowpass filter from the lowpass filter pull-down list 

.

7.5 Pretest Phase

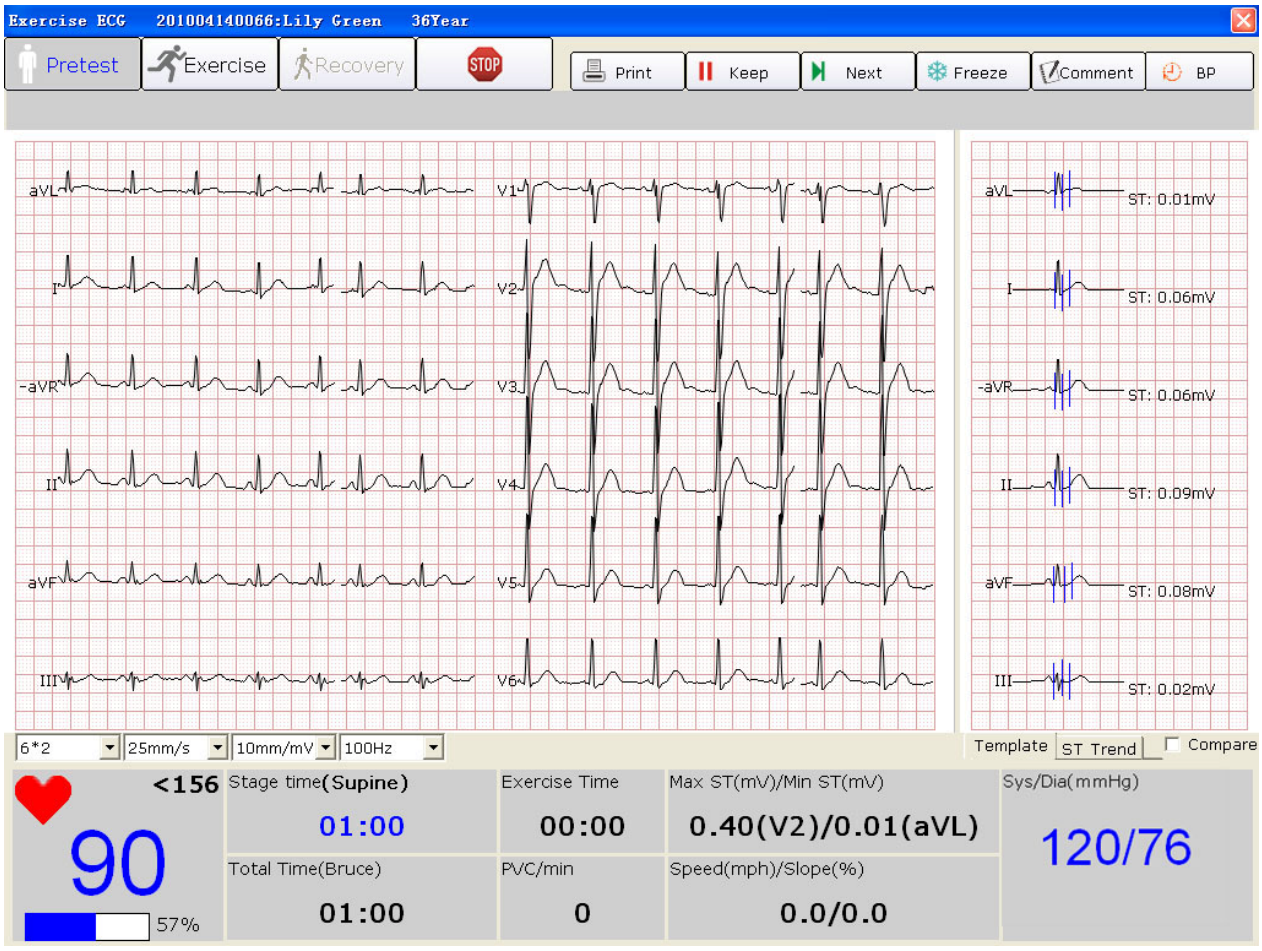
Notes:

1. If the test time exceeds 40 minutes, the system will enter the monitoring status. Data will not be saved or printed any more.

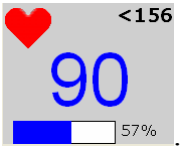
2. The length of the pretest phase is not fixed, but it should be no less than 15 seconds.

When the tracings are satisfying and you have specified the desired settings, you can start the pretest.

Click on the **Pretest** button on the pre-sampling interface (Figure 7-1) to enter the pretest phase.



7.5.1 Viewing the Heart Rate and the Blood Pressure

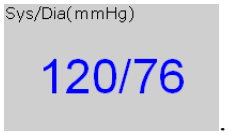
1. View the heart rate in the heart rate field 

. The middle number is the current heart rate, and the right number is the target heart rate.

The symbol

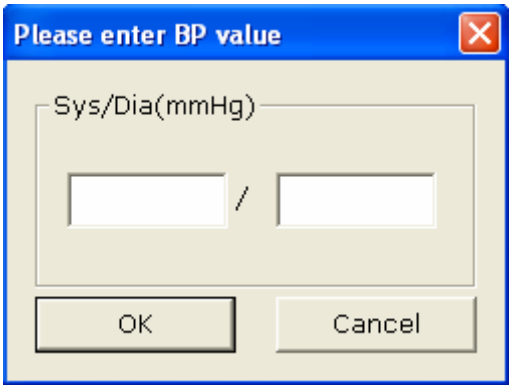
shows the percentage of the current heart rate to the target heart rate, and the blue part indicates the current heart rate.

Note: If the current heart rate exceeds the target heart rate, the hint *The current HR has exceeded the target HR!* will appear on the sampling interface and the background color of the heart rate field will change from white to yellow.

2. View the blood pressure in the BP field 

. The left number is the systolic pressure, and the right number is the diastolic pressure. The displayed blood pressure will be updated every set time period. Clicking on the **BP** button can update the displayed blood pressure manually.

Double-click on the BP field on the ECG sampling interface to open the following dialog box, and then enter the blood pressure manually. If you set the BP sampling mode to **Manually Enter BP** on the **Exercise ECG Setting** interface, clicking on the **BP** button can also open the following dialog box.



Note: If the systolic pressure or the diastolic pressure exceeds the normal BP range, the hint *The systolic/diastolic BP has exceeded the normal range!* will appear on the sampling interface and the background color of the BP field will change from white to yellow.

7.5.2 Viewing Other Information

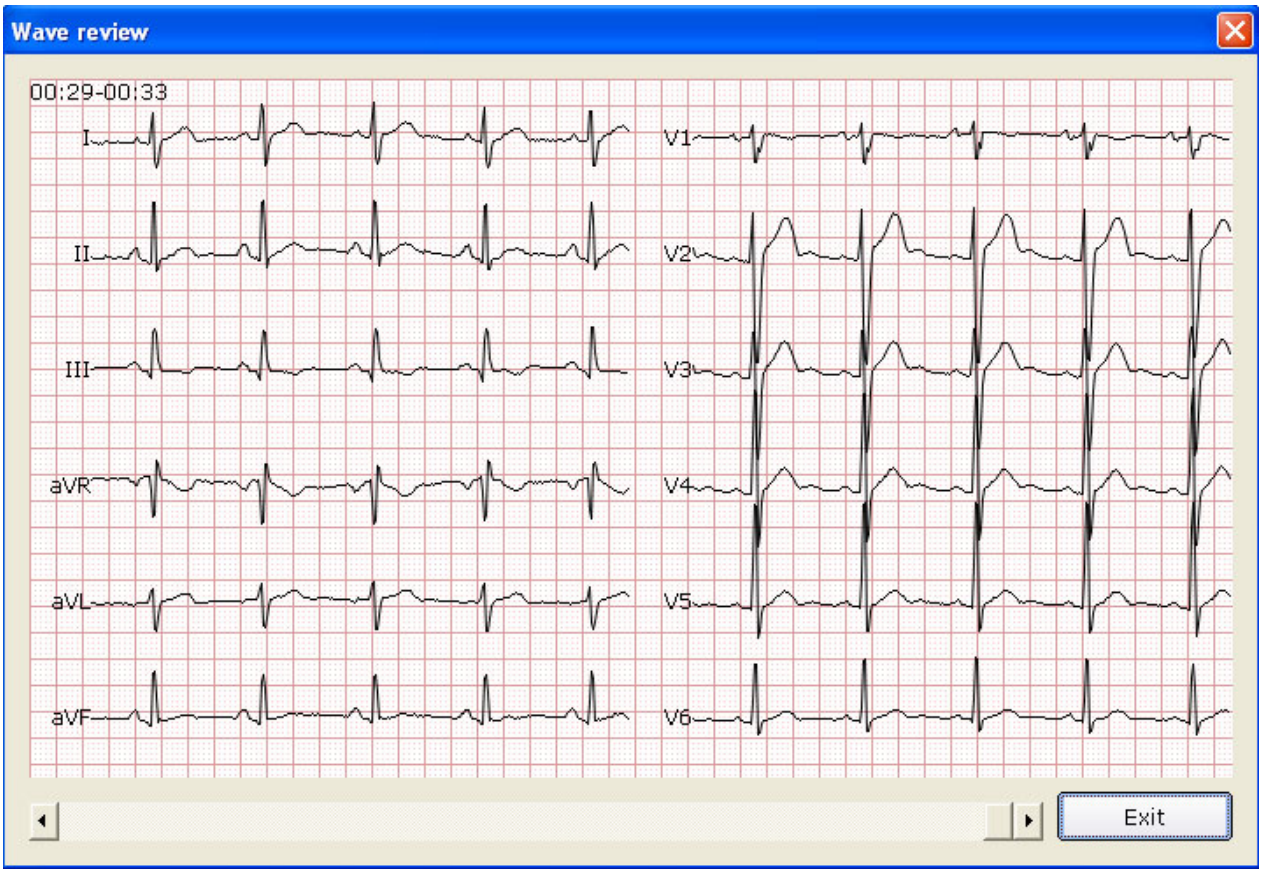
1. If a treadmill is used, view other information such as the stage time, exercise time, total time, PVC/min, speed/slope, and Max ST/Min ST.

2. If an ergometer is used, view other information such as the stage time, exercise time, total time, power/RPM, and Max ST/Min ST.

Note: Total time is counted from the beginning of the pretest phase to the end of the exercise test.

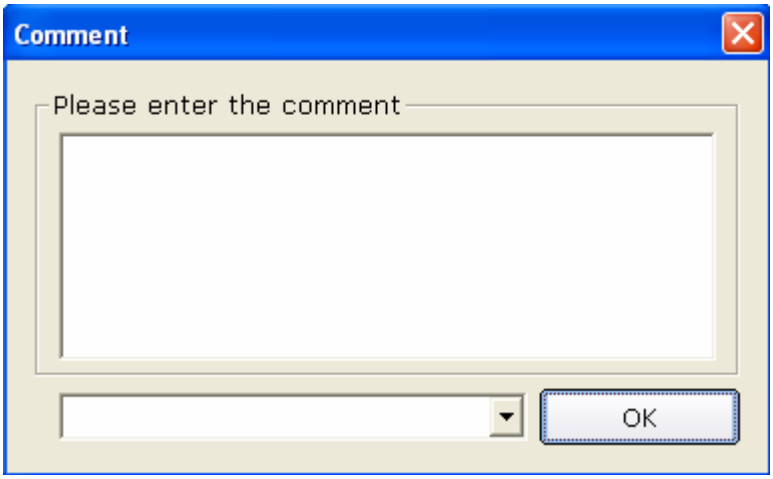
7.5.3 Editing the Waveform

1. Click on the **Freeze** button to freeze waves on the current screen, and the **Wave review** interface pops up.

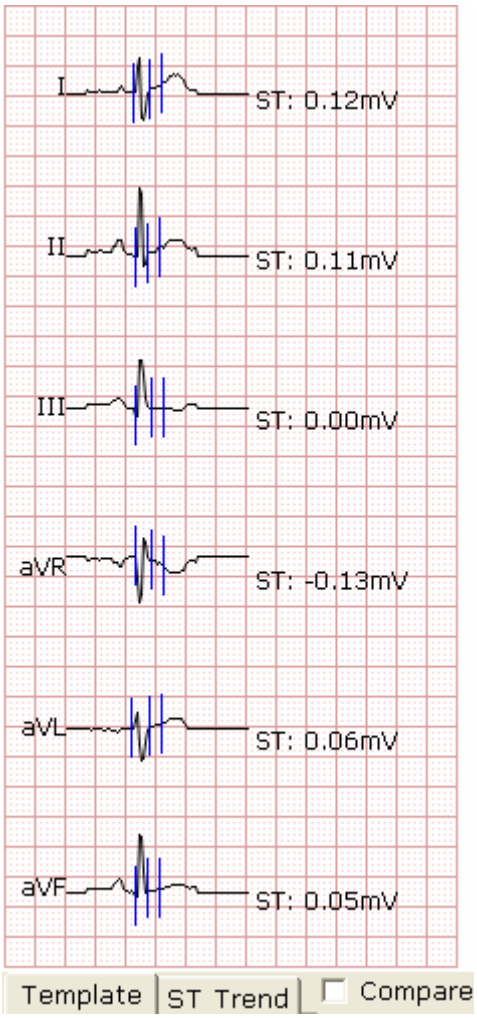


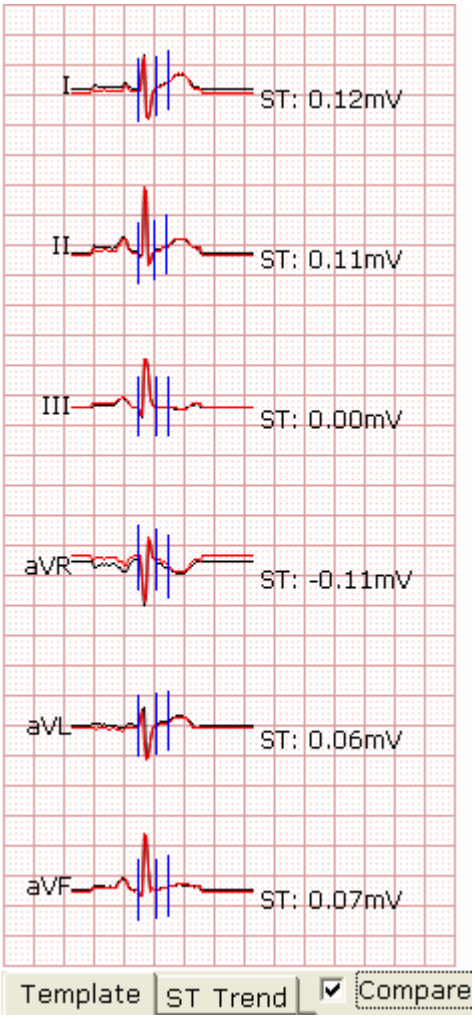
Click on **Exit** to return to the ECG sampling interface.

2. Click on the **Comment** button to display the **Comment** dialog box. Enter the comment in the **Comment** dialog box. Click on the **OK** button, and the comment will be displayed on the ECG waves on the analysis interface.

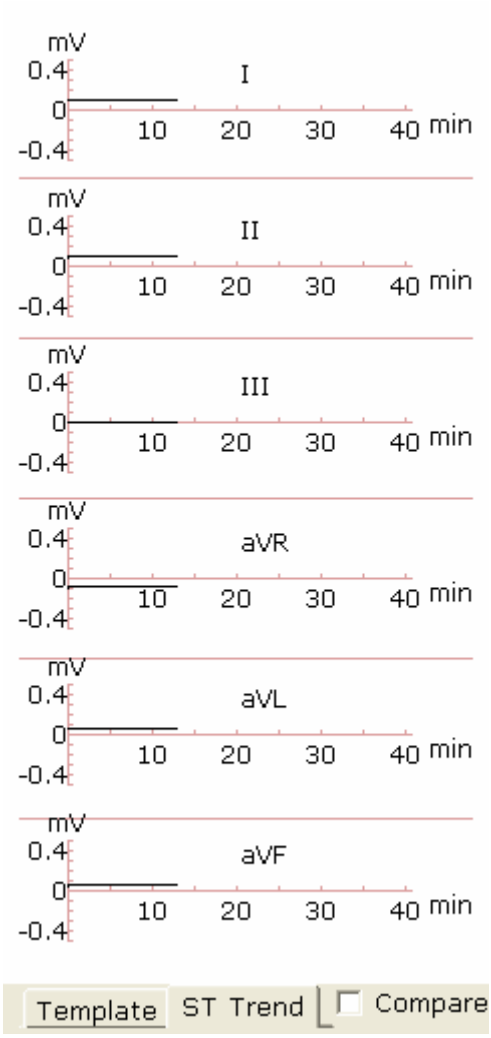


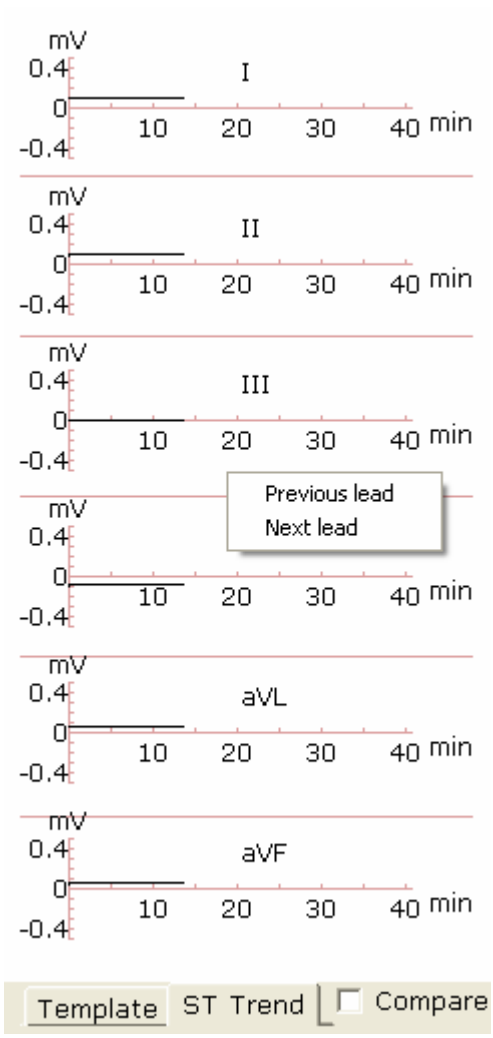
3. Click on the **Template** button, and the average waves of 12 leads and the calibration lines will be displayed. The average waves will be updated every 10 seconds. Right-click on the average wave field to display the lead group menu, and then you can select other leads. Select **Compare** to compare the current ST segments with the average beats of the sampled data in the first stage of the pretest phase. Double-click on the average wave of a lead, the amplified average wave of the lead and the calibration lines will be displayed. You can drag the calibration lines on the wave. The average wave will be updated every 10 seconds.





4. Click on the **ST Trend** button to display the ST trend. Right-click on the ST trend field to display the lead group menu, and then you can select other leads.





7.5.4 Printing the Pretest Report

1. The pretest report will be printed automatically 14 seconds after the beginning of the pretest phase.

2. Or you can click on the **Print** button to print the pretest report.

7.6 Exercise Phase

Note: If the test time exceeds 40 minutes, the system will enter the monitoring status. Data will not be saved or printed any more.

1. Instruct the patient to use the treadmill/ergometer. Then click on the **Exercise** button to enter the exercise phase. Or the system will enter the exercise phase automatically after reaching the set pretest time.

2. View the heart rate and BP of the patient. For details, see Section 7.5.1, "Viewing the Heart Rate and the Blood Pressure".

Notes:

1. If the current heart rate exceeds the target heart rate, the hint *The current HR has exceeded the target HR!* will appear on the sampling interface and the background color of the heart rate field will change from white to yellow.

2. When the current heart rate exceeds the target heart rate, click on the **Recovery** button to enter the recovery phase and observe the waveforms.

3. View other information. For details, see Section 7.5.2, "Viewing Other Information".

4. Edit the waveform. For details, see Section 7.5.3, "Editing the Waveform".

5. Click on the **Print** button to print the exercise report.

6. The system will enter the next stage of the exercise phase automatically after the set time of this stage is over. Or click on the **Exercise** or **Next** button to enter the next stage of the exercise phase manually.

7. Click on the **Keep** button and the system enters the **Keep** state. The hint *Keep* will be displayed in the speed/power field. The **Next** button becomes unavailable. In this state, the system will not follow the previous settings to change the speed and grade of the treadmill, but keep the current speed and grade until this button is pressed again.

7.7 Recovery Phase

1. When the current heart rate exceeds the target heart rate, click on the **Recovery** button to enter the recovery phase. Or the system will enter the recovery phase automatically after the set exercise test time is over.

2. View the heart rate and BP of the patient. For details, see Section 7.5.1, "Viewing the Heart Rate and the Blood Pressure".

Note: If the current heart rate exceeds the target heart rate, the hint *The current HR has exceeded the target HR!* will appear on the sampling interface and the background color of the heart rate field will change from white to yellow.

3. View other information. For details, see Section 7.5.2, "Viewing Other Information".

4. Edit the waveform. For details, see Section 7.5.3, "Editing the Waveform".

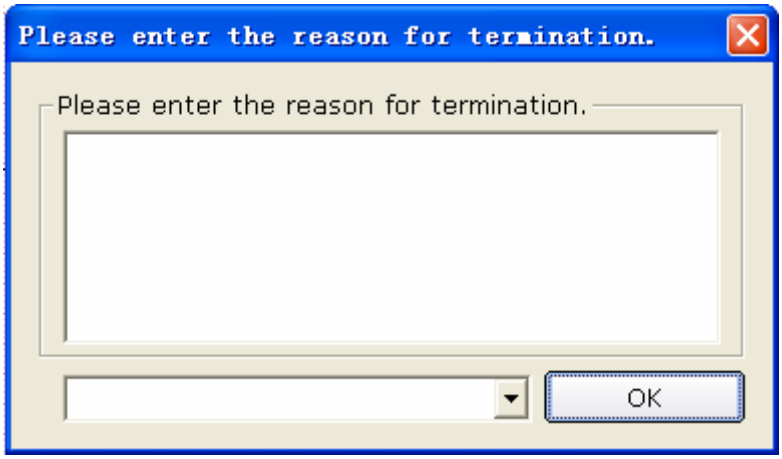
5. Click on the **Print** button to print the recovery report.

6. The system will enter the next stage of the recovery phase automatically after the set time of this stage is over. Or click on the **Recovery** button or click on the **Next** button to enter the next stage of the recovery phase manually.

Note: If the test time exceeds 40 minutes, the system will enter the monitoring status. Data will not be saved or printed any more.

7.8 Exiting the Exercise Test

During the exercise test, click on the **STOP** button to display the following dialog box. Enter the reasons for termination in the dialog box or select a reason from the pull-down list. Then click on the **OK** button to open the analysis interface. The reason for termination will be displayed in the summary report.



7.9 About Analysis Interface

7.9.1 About Summary Interface

1. Click on **Summary** to open the summary interface.

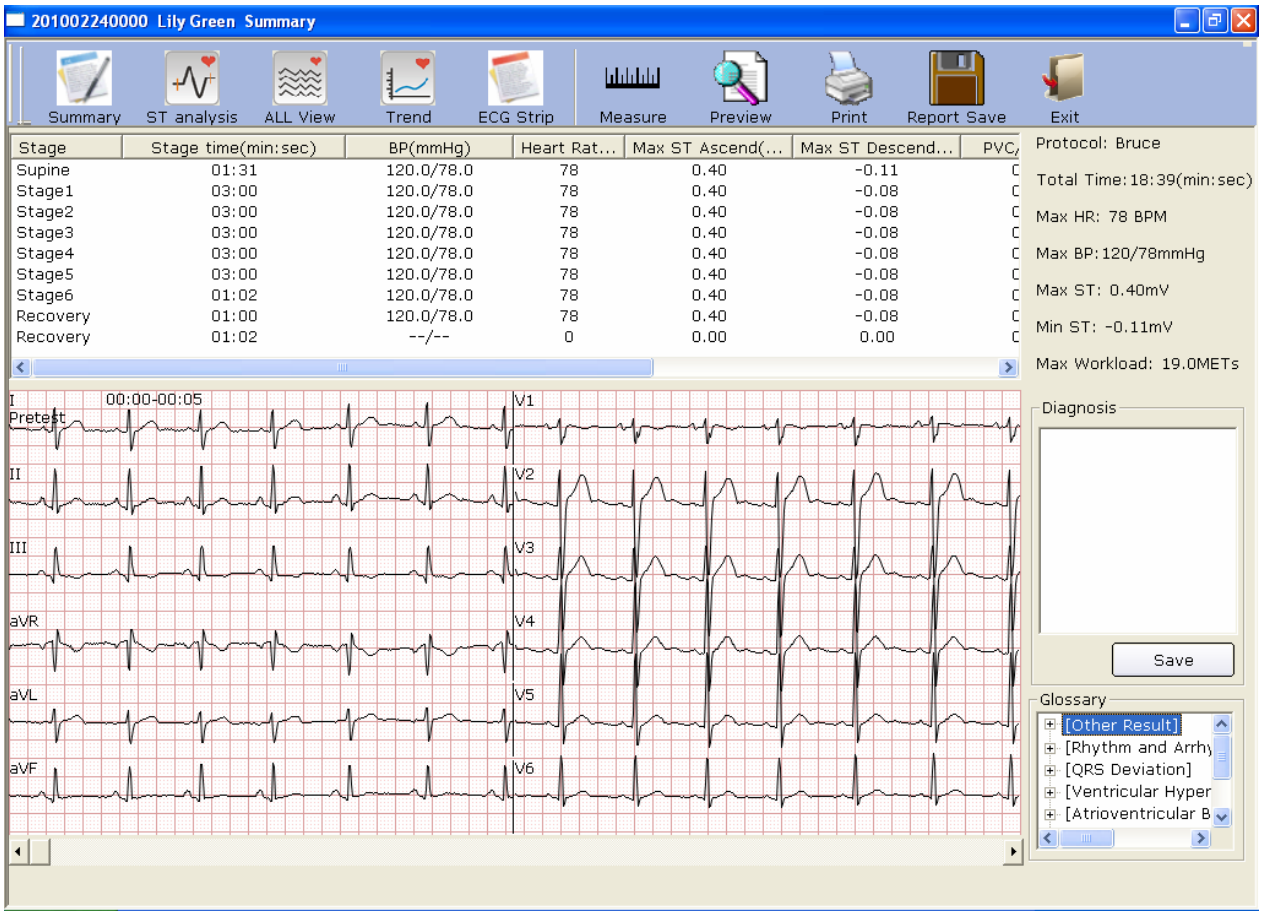


Figure 7-2 Summary Interface

Click on the **Measure** button and then click on one point on the wave, and then drag the mouse to another point. The distance, amplitude difference and heart rate between the two points will be displayed.

2. If a treadmill is used, view the stage, stage time, speed, slope, workload (METs), BP, HR, PVC, Max ST and Min ST in every stage of the exercise test in the list.

If an ergometer is used, view the stage, stage time, power, BP, HR, PVC, Max ST and Min ST in every stage of the exercise test in the list.

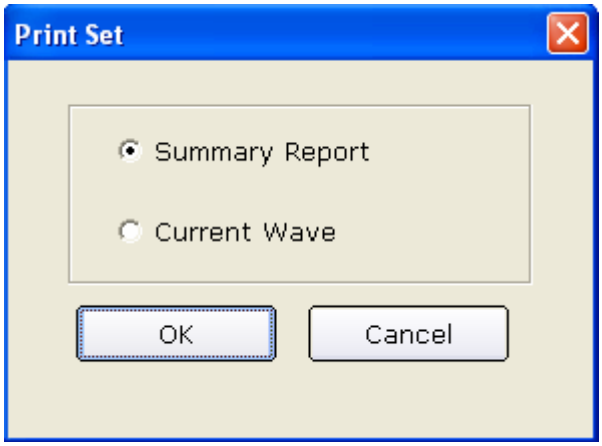
3. Click on a stage, the scroll bar of the wave field will be scrolled to the ECG waves of the stage.

4. Right-click on a wave, and then click on the pop-up **Add Comment** menu. Then you can enter the comment in the **Comment** dialog box. Click on the **OK** button, and the comment will be displayed on the wave.

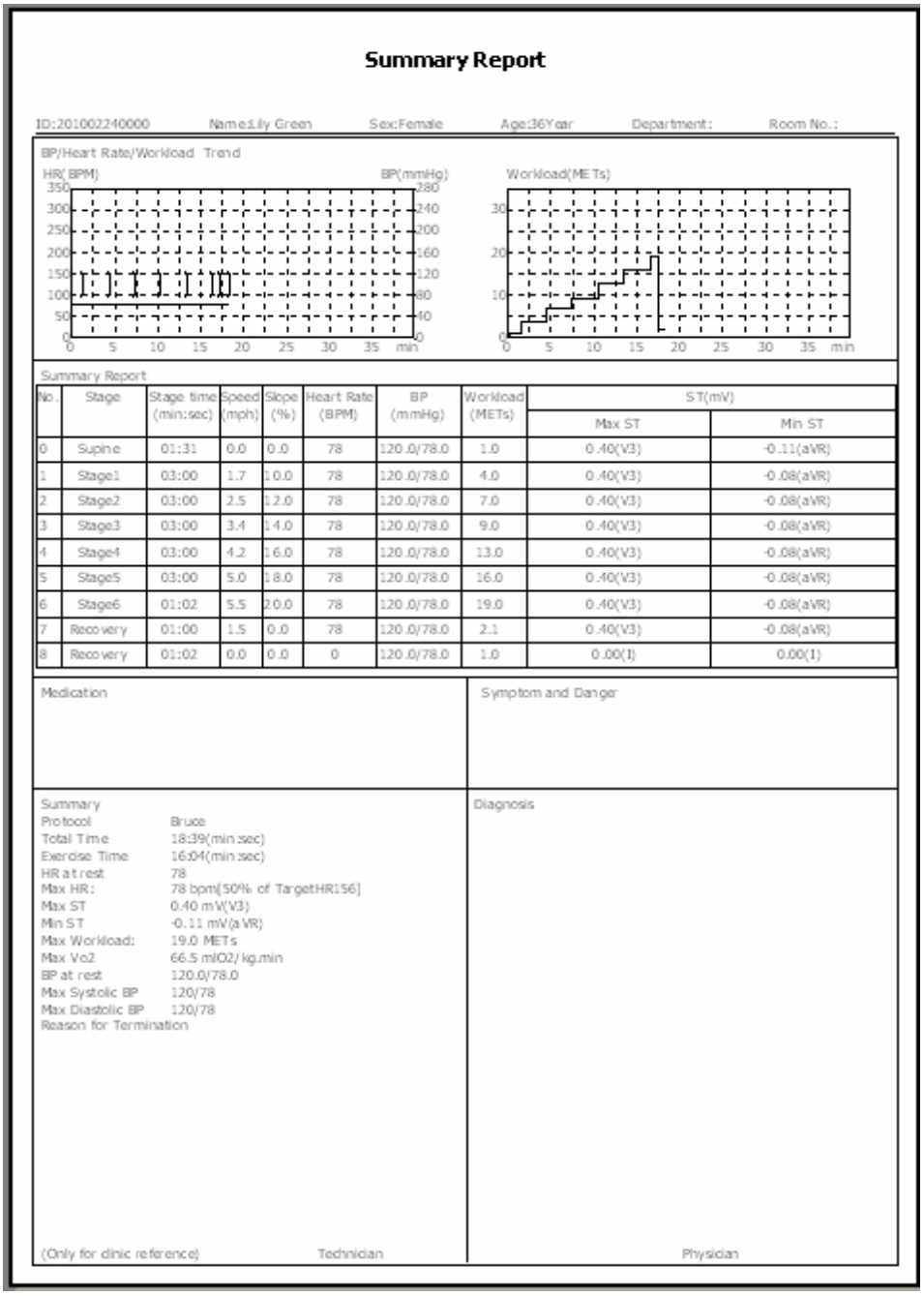
5. Enter diagnosis results in the **Diagnosis** textbox, and then click on **Save**.

6. Or double-click on the necessary results required to be added in the **Glossary** textbox, and the selected results will be displayed in the **Diagnosis** textbox, and then click on the **Save** button.

7. Click on the **Preview** button to display the **Print Set** window.



Select **Summary Report** or **Current Wave**. Click on the **OK** button to open the preview interface.



Summary Report

ID:201002240000 Name:Lily Green Sex:Female Age:36Year Department: Room No.:

BP/Heart Rate/Workload Trend

Summary Report

No.	Stage	Stage time (min:sec)	Speed (mph)	Slope (%)	Heart Rate (BPM)	BP (mmHg)	Workload (METs)	ST(mV)	
								Max ST	Min ST
0	Supine	01:31	0.0	0.0	78	120.0/78.0	1.0	0.40(V3)	-0.11(aVR)
1	Stage1	03:00	1.7	10.0	78	120.0/78.0	4.0	0.40(V3)	-0.08(aVR)
2	Stage2	03:00	2.5	12.0	78	120.0/78.0	7.0	0.40(V3)	-0.08(aVR)
3	Stage3	03:00	3.4	14.0	78	120.0/78.0	9.0	0.40(V3)	-0.08(aVR)
4	Stage4	03:00	4.2	16.0	78	120.0/78.0	13.0	0.40(V3)	-0.08(aVR)
5	Stage5	03:00	5.0	18.0	78	120.0/78.0	16.0	0.40(V3)	-0.08(aVR)
6	Stage6	01:02	5.5	20.0	78	120.0/78.0	19.0	0.40(V3)	-0.08(aVR)
7	Recovery	01:00	1.5	0.0	78	120.0/78.0	2.1	0.40(V3)	-0.08(aVR)
8	Recovery	01:02	0.0	0.0	0	120.0/78.0	1.0	0.00(I)	0.00(I)

Medication

Symptom and Danger

Summary

Protocol	Bruce
Total Time	18:39(min:sec)
Exercise Time	16:04(min:sec)
HR at rest	78
Max HR:	78 bpm[50% of TargetHR156]
Max ST	0.40 mV(V3)
Min ST	-0.11 mV(aVR)
Max Workload:	19.0 METs
Max Vo2	66.5 ml/O2/kg.min
BP at rest	120.0/78.0
Max Systolic BP	120/78
Max Diastolic BP	120/78

Reason for Termination

Diagnosis

(Only for clinic reference) Technician Physician

Figure 7-3 Summary Report

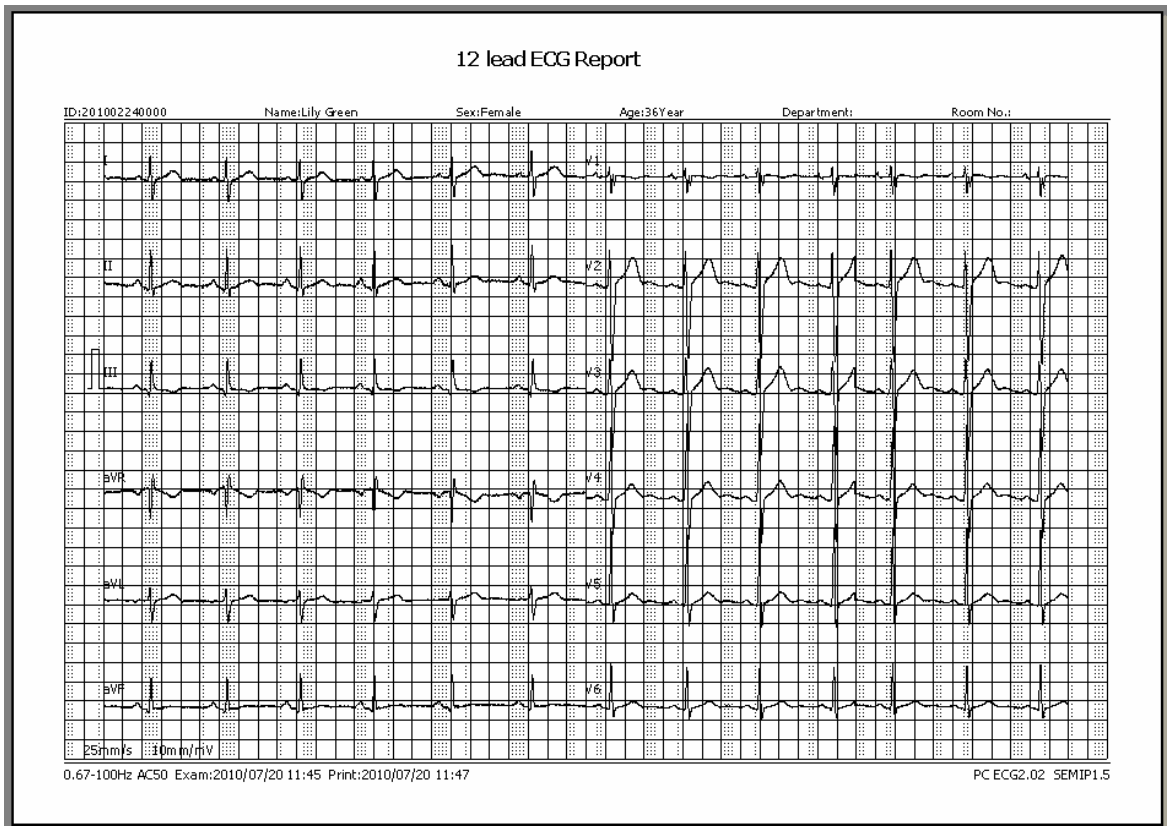


Figure 7-4 Current Wave Report

Note: The diagnosis result is displayed in the diagnosis field of the summary report.

7.9.2 About ST Analysis Interface

1. Click on the **ST analysis** button to display the ST analysis interface.

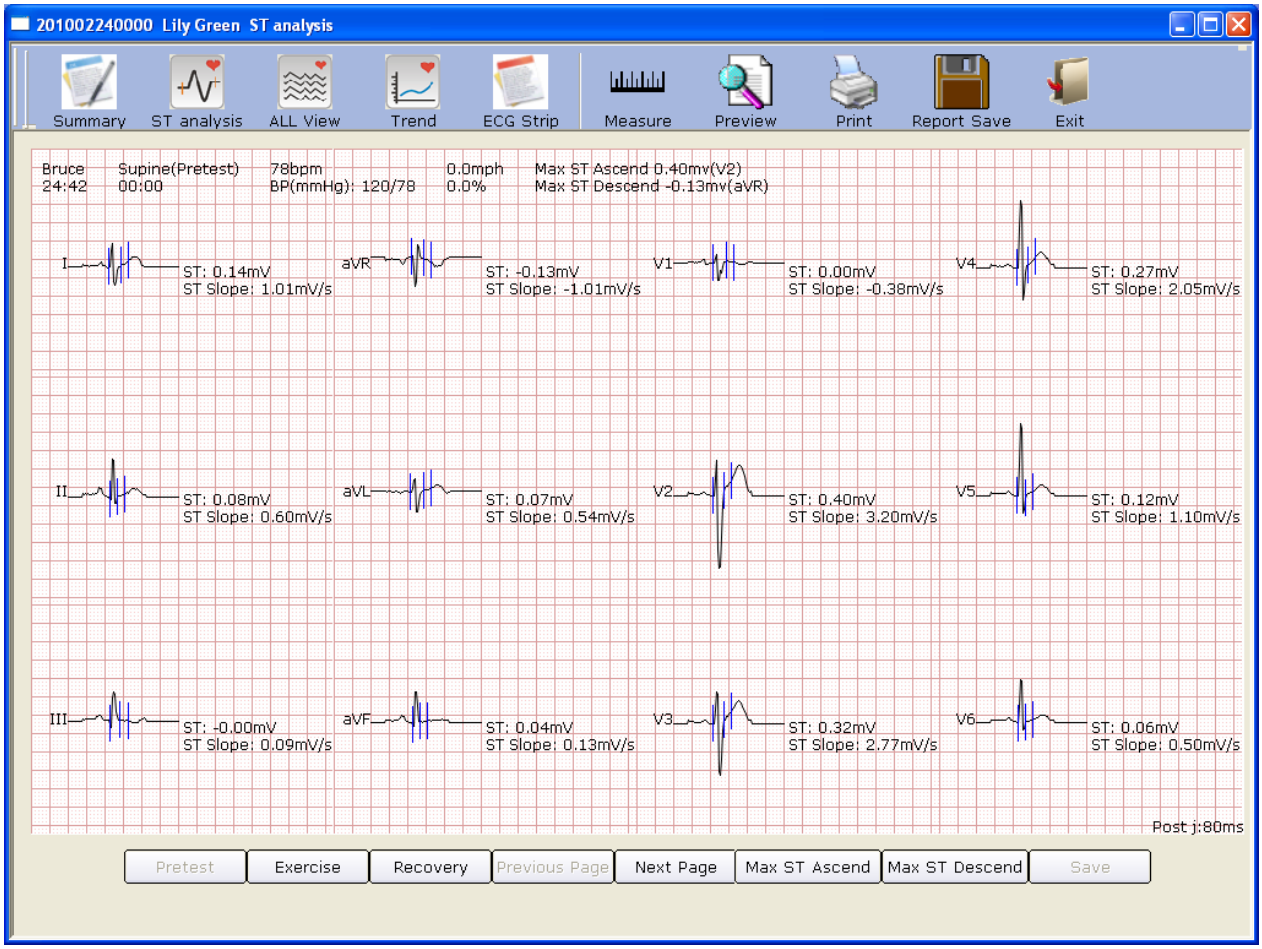


Figure 7-5 ST Analysis Interface

2. Click on **Pretest** to display 12-lead ST analysis waves of the pretest phase.

3. Click on **Exercise** to display 12-lead ST analysis waves of the exercise phase.

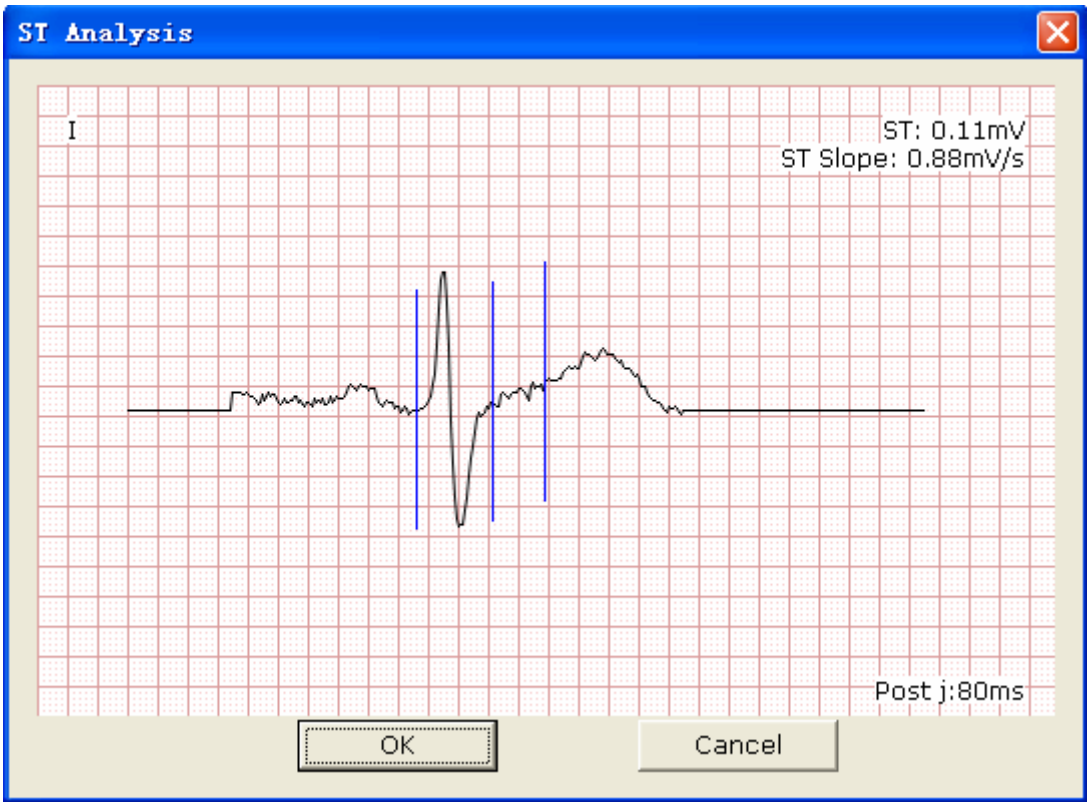
4. Click on **Recovery** to display 12-lead ST analysis waves of the recovery phase.

5. Click on **Previous Page**/**Next Page** to display 12-lead ST analysis waves of every 10 seconds.

6. Click on **Max ST Ascend** to display the Max ST ascending waves.

7. Click on **Max ST Descend** to display the Max ST descending waves.

8. Double-click on the wave of a lead, the amplified wave of the lead and the calibration lines will be displayed. Drag the calibration lines on the wave, and the ST value will change. Click on the **OK** button, and then the **Save** button becomes available. Click on **Save** to save the modifications.



7.9.3 About All View Review Interface

1. Click on the **All View** button to display the all view interface.

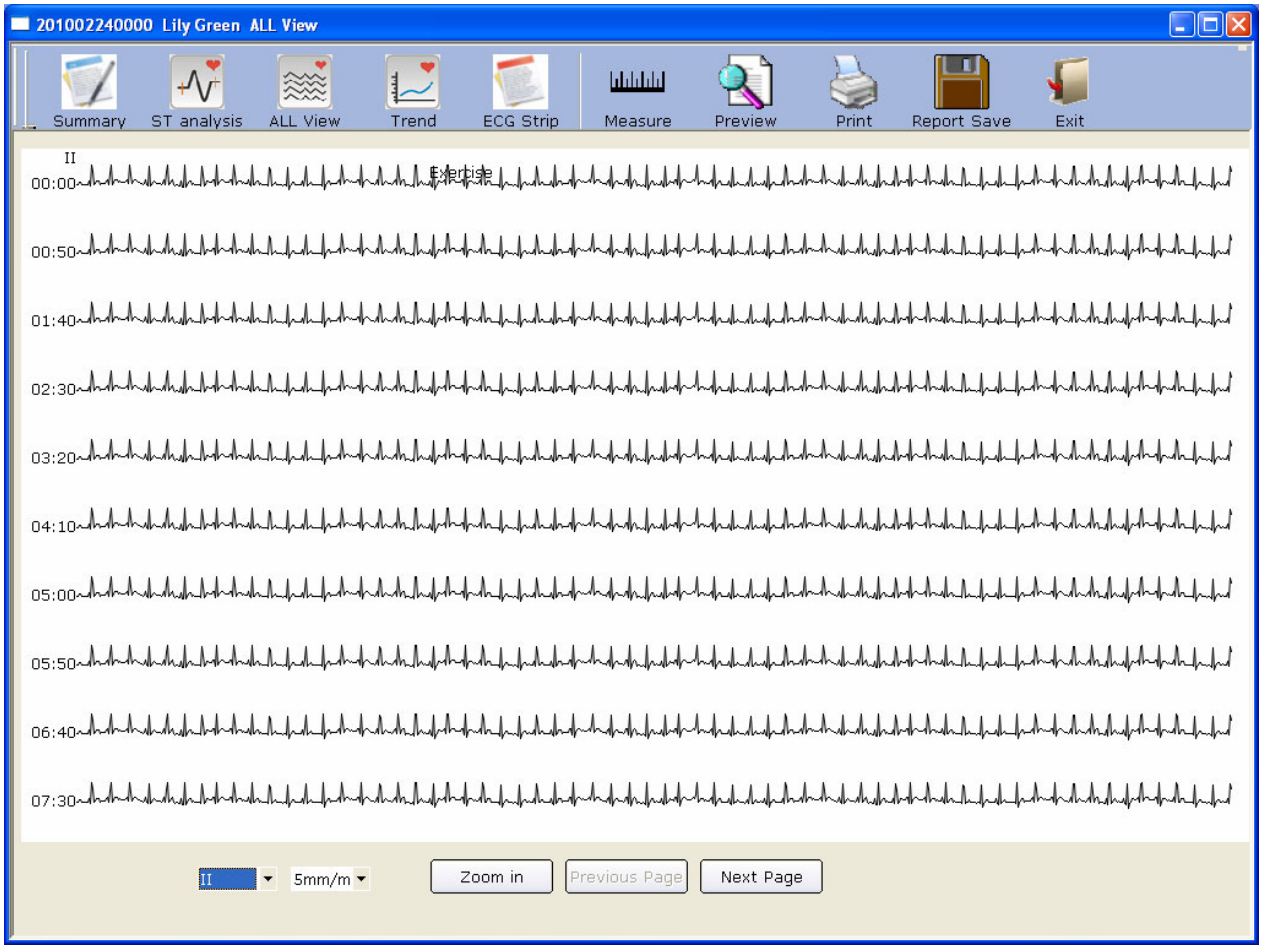
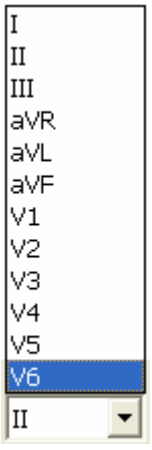
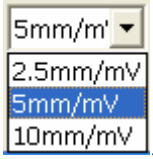


Figure 7-6 All View Interface

The all view interface displays the ECG wave of one lead from the beginning of the exercise test to the end.

2. Select a lead from the lead pull-down list 

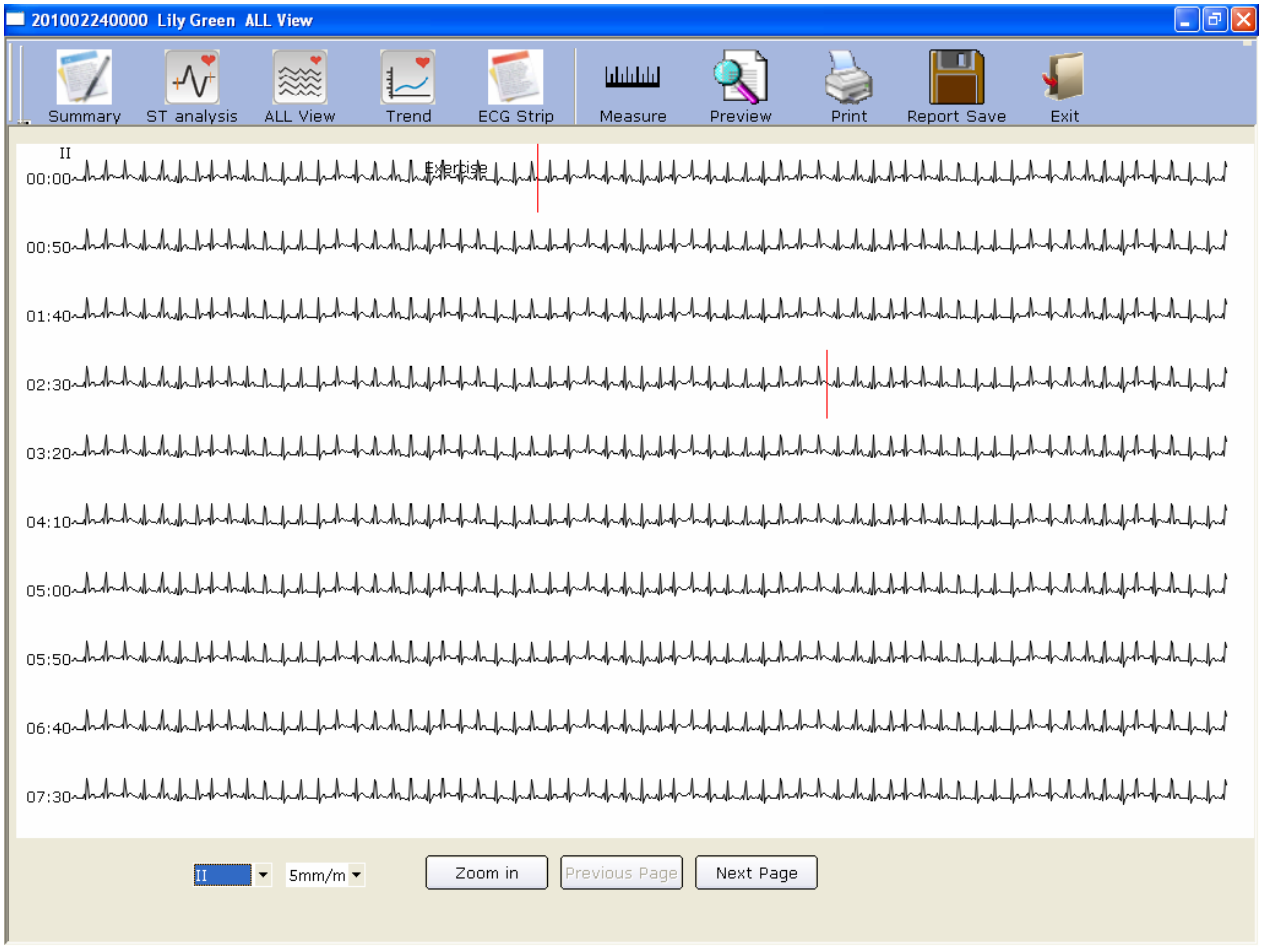
to view the ECG wave of the lead.

3. Select a gain from the gain pull-down list 

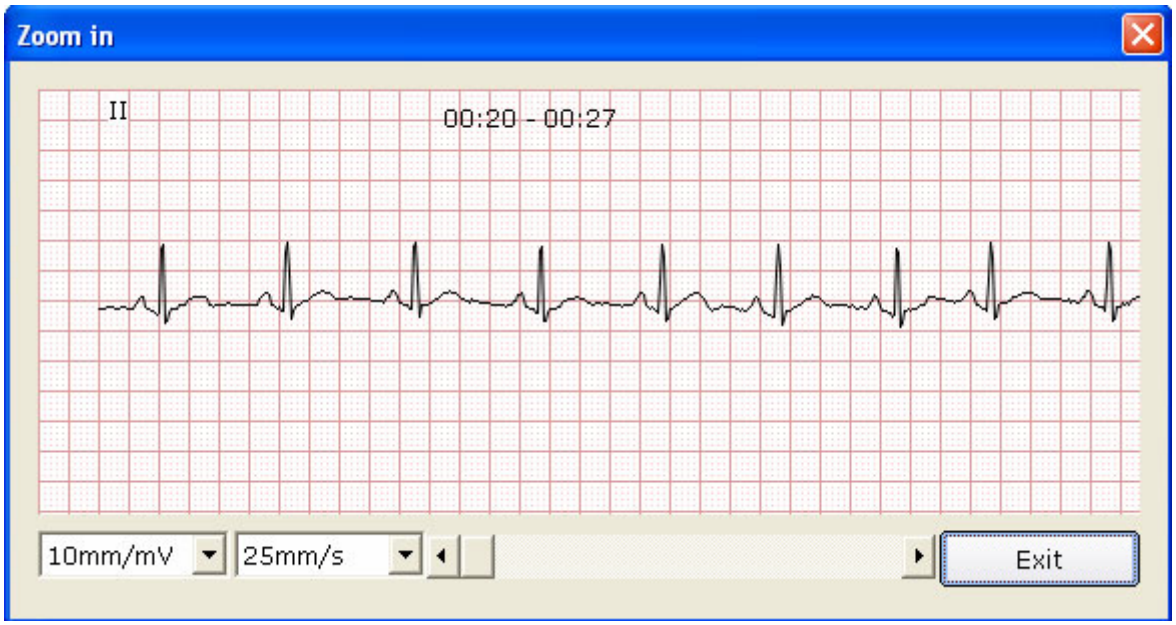
.

4. Click on one point on the wave and drag the mouse to another point, and then the selected

range will be marked with two red lines.



Then click on the **Zoom in** button to display the amplified ECG segment.



Drag the bottom scroll bar to view the whole amplified ECG waves.

5. The all view interface displays ECG waves of 400 seconds. ECG waves exceeding 400

seconds can be reviewed by clicking on the **Previous Page/Next Page** button.

7.9.4 About Trend Interface

Click on the **Trend** button to display the trend interface.

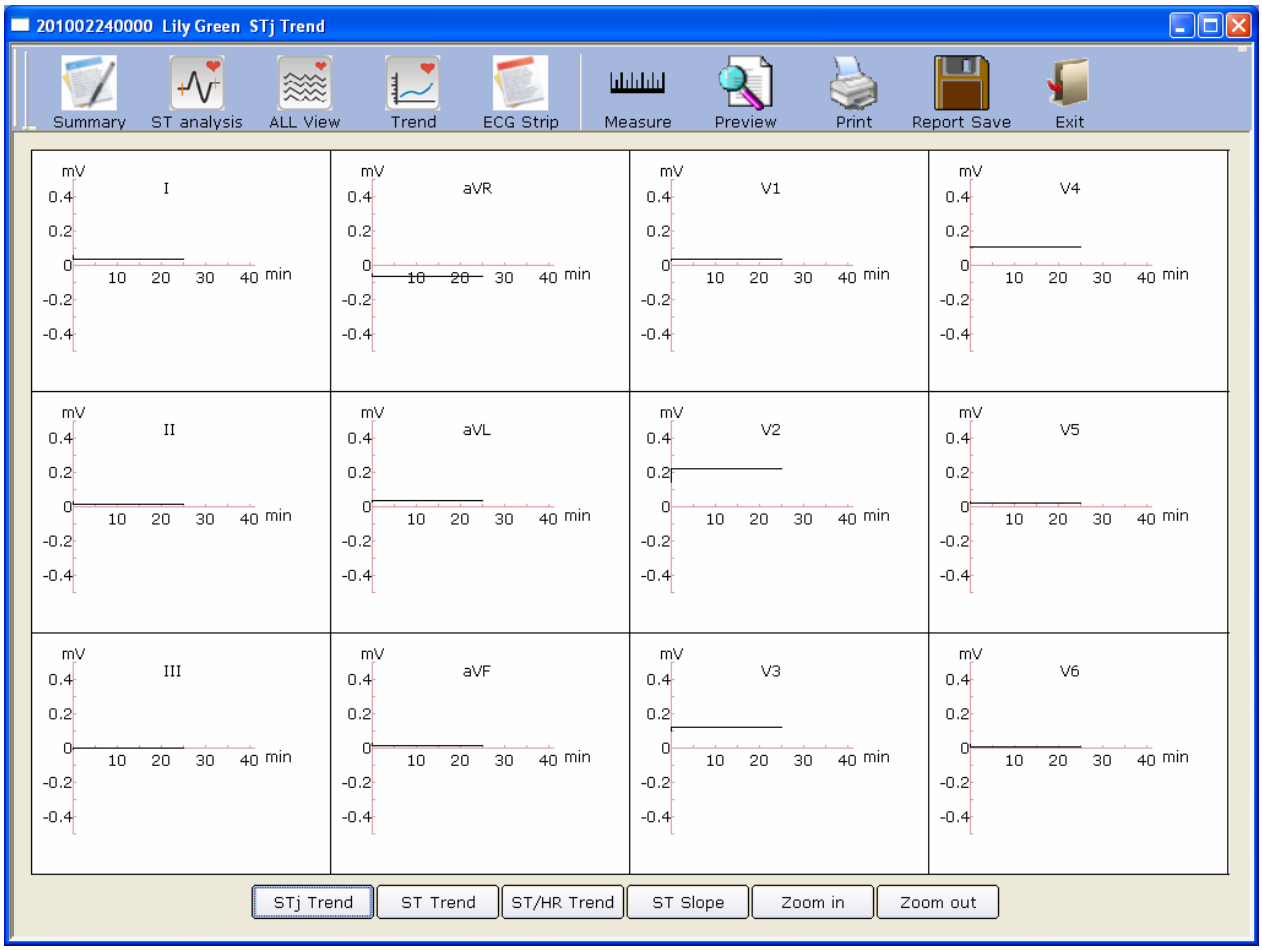


Figure 7-7 Trend Interface

You can observe 12-lead trend of the exercise test on the trend interface.

The horizontal coordinates indicate test time, but the units of the vertical coordinates are different on different trend interfaces.

7.9.5 About ECG Strip Interface

Click on the **ECG Strip** button to display the ECG strip interface.

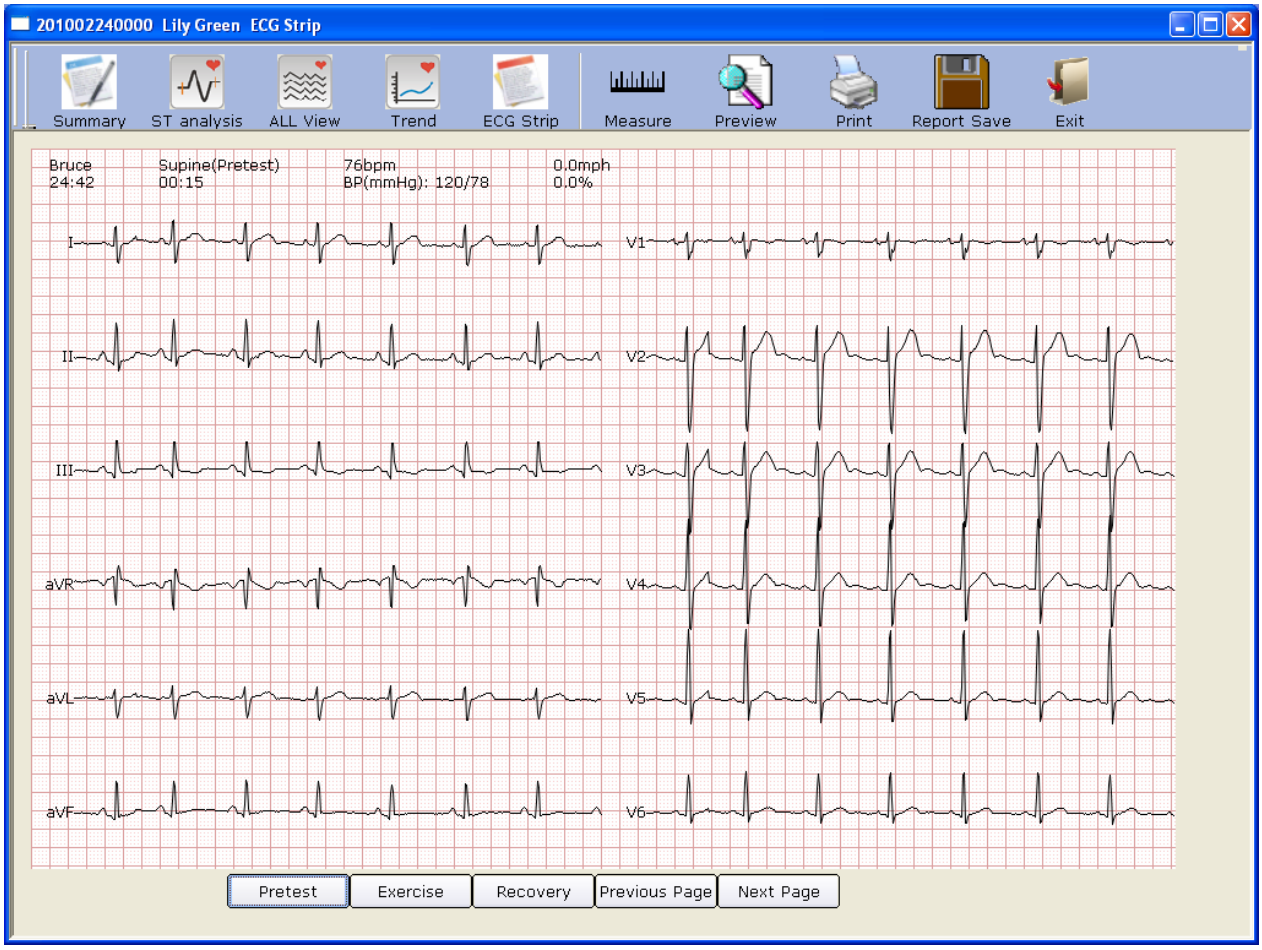


Figure 7-8 ECG Strip Interface

1. Click on **Pretest** to display strip waves of the pretest phase.
2. Click on **Exercise** to display strip waves of the exercise phase.
3. Click on **Recovery** to display strip waves of the recovery phase.
4. Click on **Previous Page**/**Next Page** to display strip waves of every 30 seconds.

7.9.6 Previewing ECG Reports

Click on the **Preview** button to preview an ECG report.

7.9.7 Printing ECG Reports

You can print an ECG report by clicking on the **Print** button. For details, please refer to Section 6.6.10, “Printing ECG reports”.

7.9.8 Saving ECG Reports

You can save an ECG report by clicking on the **Report Save** button. For details, please refer to Section 6.6.11, “Saving ECG reports”.

7.9.9 Exiting the Analysis Interface

Click on the **Exit** button on the analysis interface to return to the initial interface.

Chapter 8 Processing Patient Records

Click on the **Data Manager** button on the initial interface (Figure 6-1) to open the **Data Manager** interface (Figure 8-1).

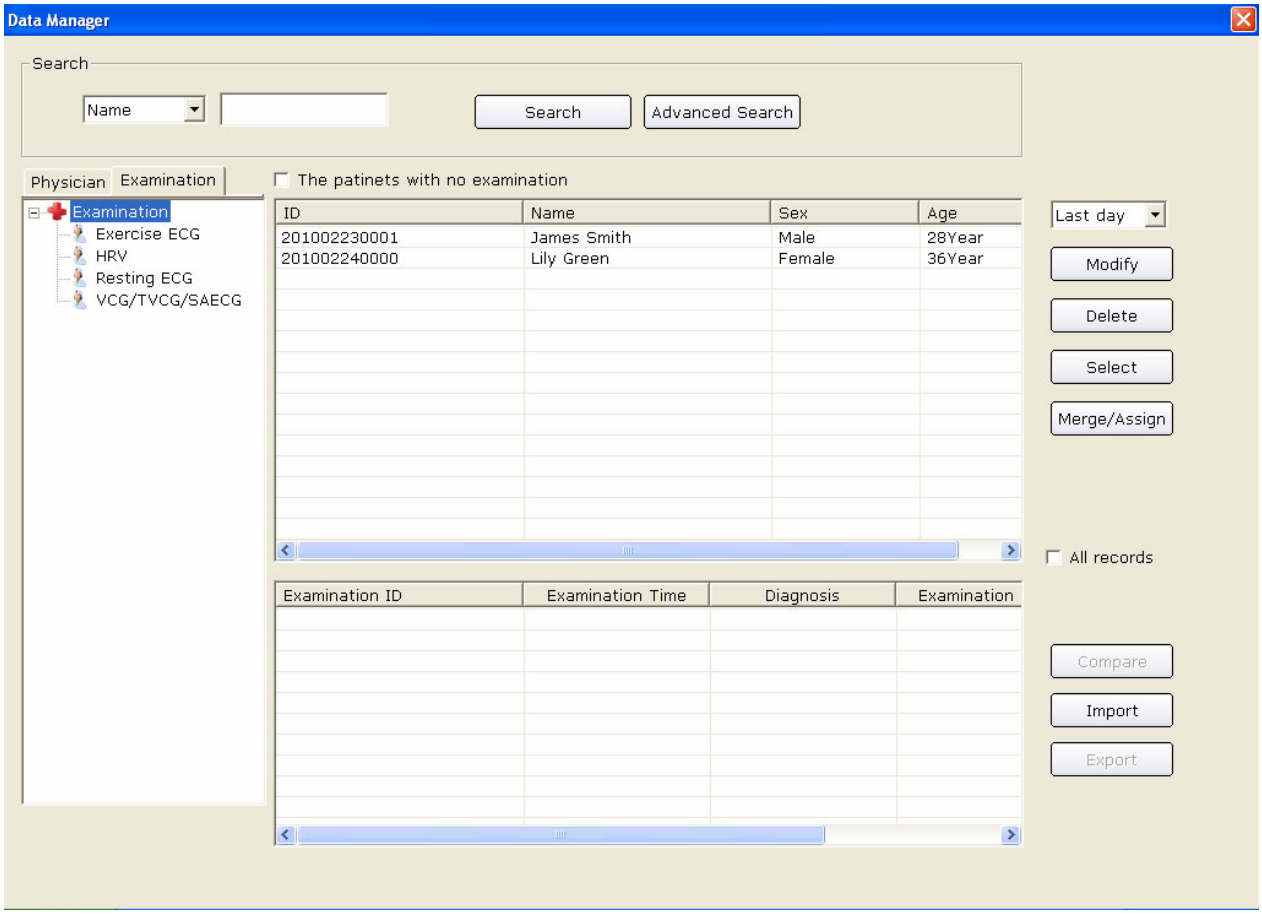
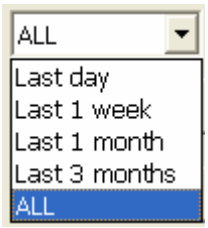


Figure 8-1 Data Manager Interface

Click on a patient record in the patient information list, and then all the examination records of the patient will be displayed in the examination record list.

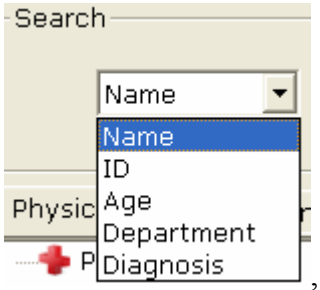
Note: Click on an option in the patient information list, such as ID, name, etc, and then all the patient records will be arranged in sequence.

8.1 Searching Patient Records

1. Select a search item in the pull-down list 

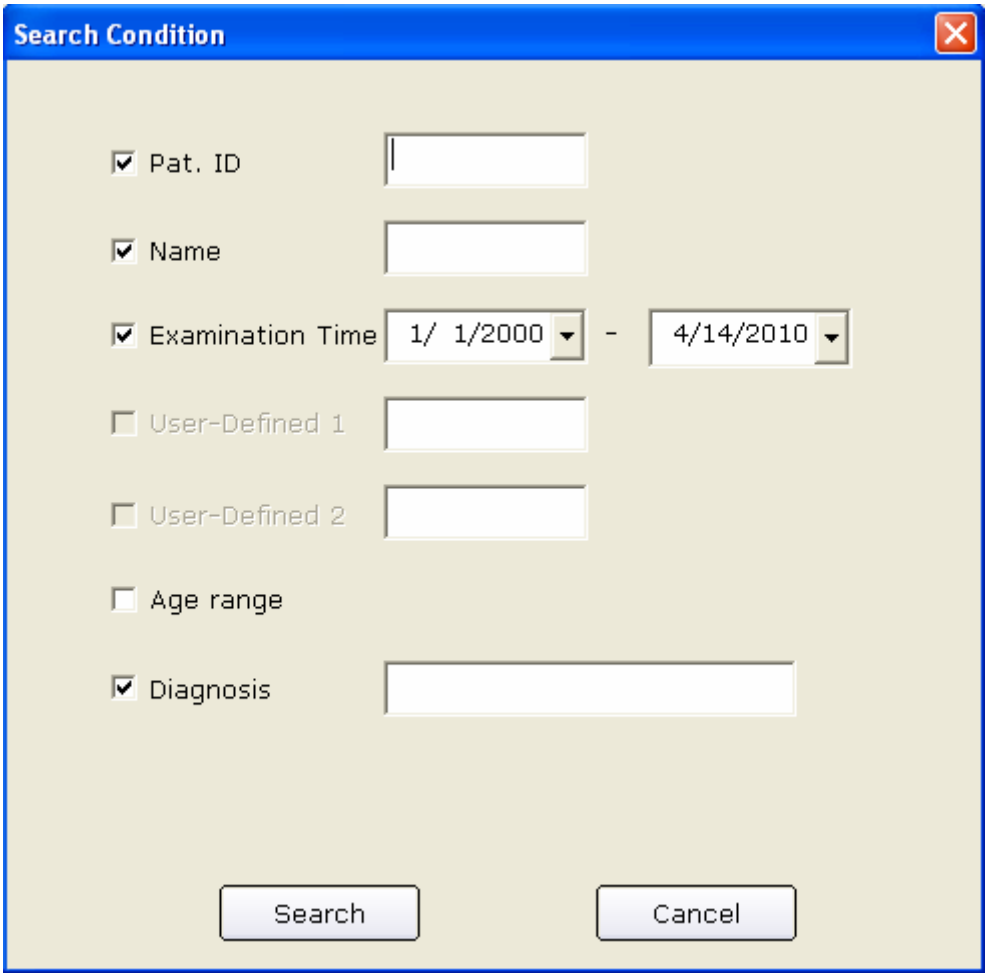
on the **Data Manager** interface. Then all the patient records which meet the search condition are listed in the patient information

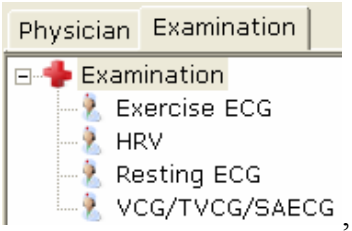
list.



2. Or select a search item in the pull-down list , enter the corresponding information in the right textbox, and then click on the **Search** button. All the patient records which meet the conditions will be displayed in the patient information list.

3. Or click on **Advanced Search** to display the **Search Condition** window. Then enter the search conditions. Click on the **Search** button, and all the patient records which meet the conditions will be displayed in the patient information list.



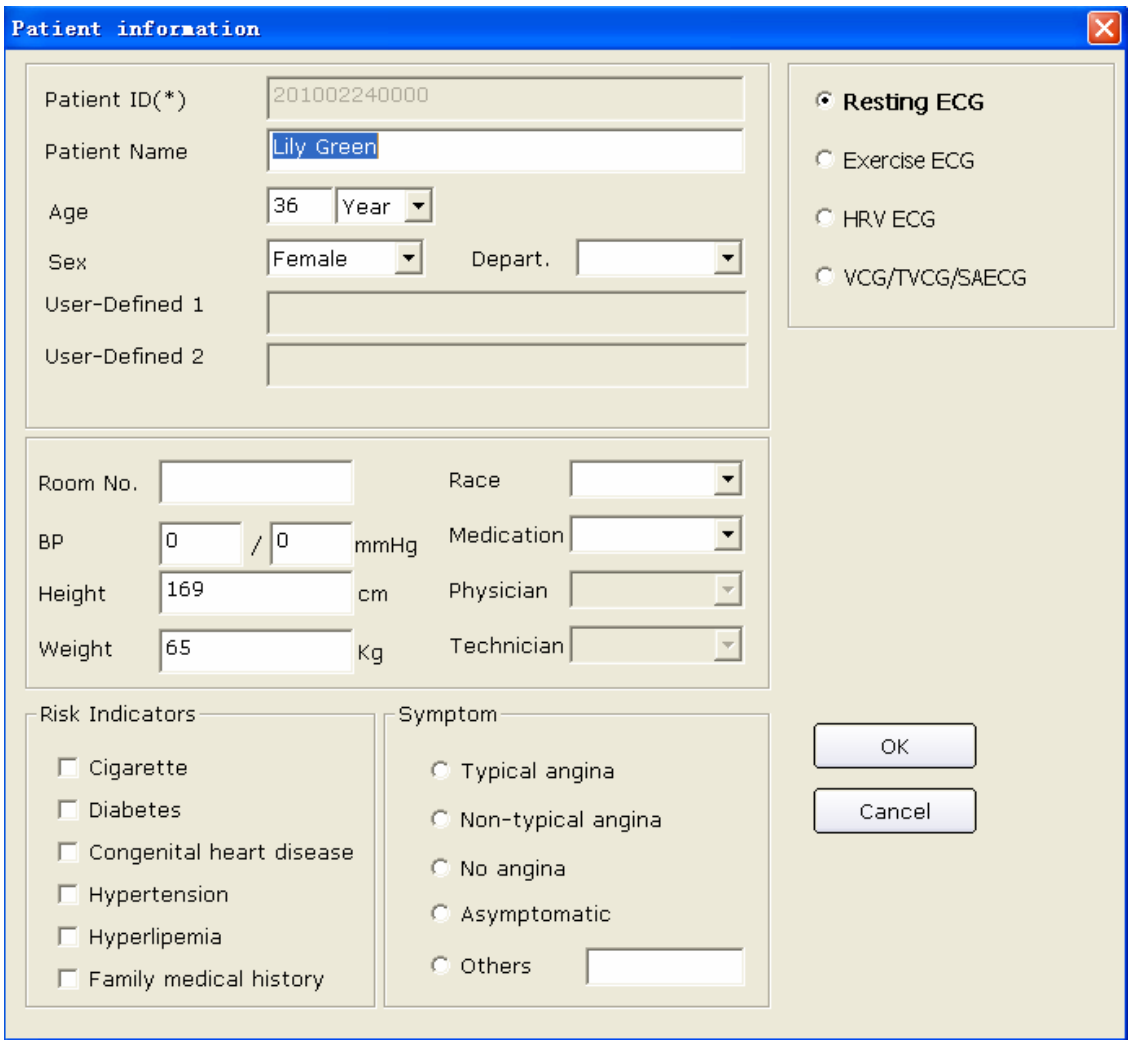


4. Or you can click on **Physician** or **Examination Record**, and choose the doctor name or examination types, all the patient records which meet the conditions will be displayed in the patient information list.

5. Select **The patients with no examination**, and then the patient records, which are registered but not examined, will appear in the patient information list.

8.2 Modifying Patient Records

Click on a patient record in the patient information list on the **Data Manager** interface, and then click on the **Modify** button to display the **Patient information** interface. Then you can modify the information of the patient on the **Patient information** interface. Click on the **OK** button to save these modifications.



8.3 Deleting Records

Note: The deletion of records is permanent, and you can't restore the records deleted. Please use this operation cautiously.

8.3.1 Deleting Patient Records

Click on a patient record in the patient information list on the **Data Manager** interface, and then click on the **Delete** button to delete the patient record from the patient information list. At the same time, all the examination records of the patient will be deleted.

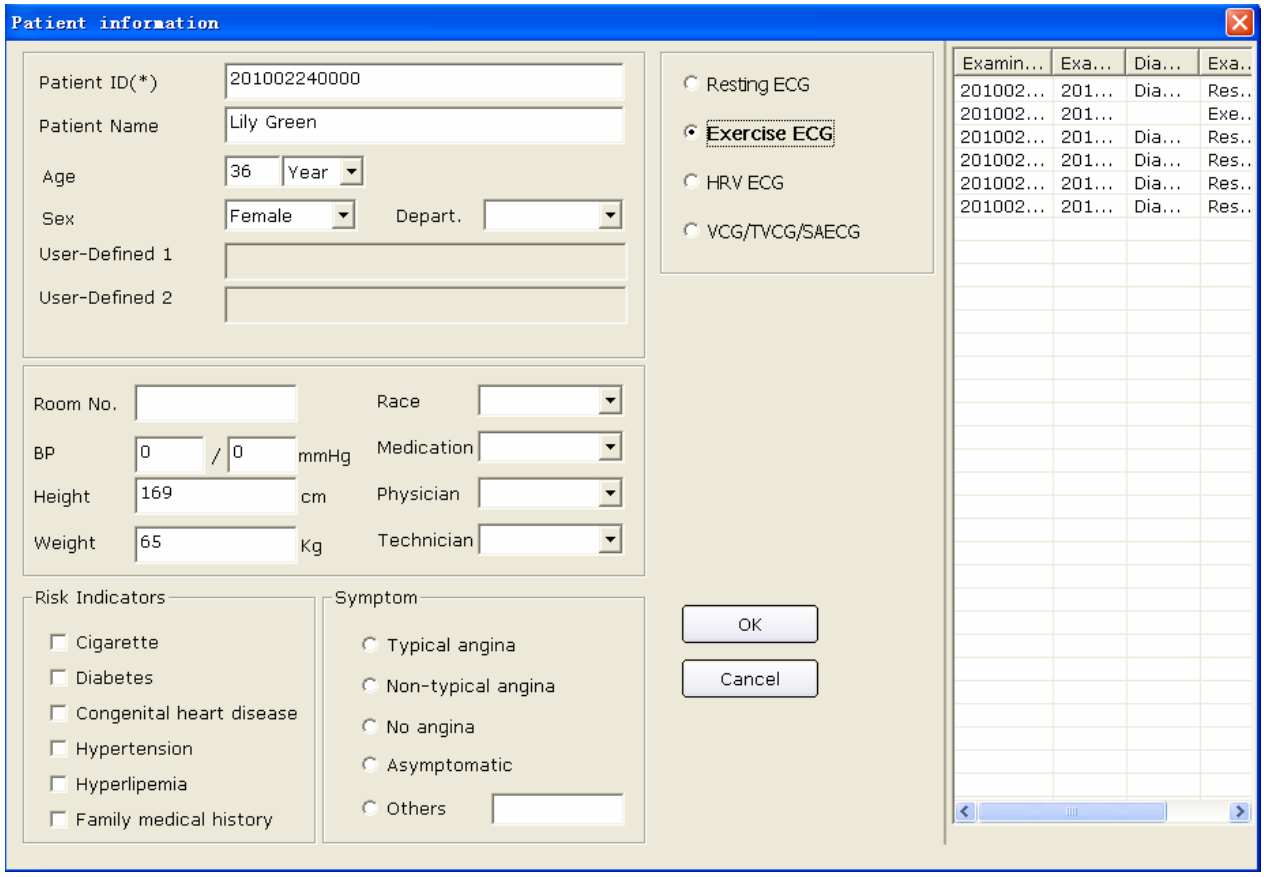
To select multiple patient records simultaneously, you can click on the first patient record to be deleted in the patient information list and press the **Shift** button on the keyboard, and then click on the last patient record to be deleted in the patient information list. You can also press the **Ctrl** button on the keyboard and then select the patient records one by one. After selecting all the patient records to be deleted, click on the **Delete** button to delete all the patient records selected from the patient information list.

8.3.2 Deleting Examination Records of a Patient

The operation methods of deleting examination records are similar to those of deleting patient records.

8.4 Selecting a Patient Record

Click on a patient record in the patient information list on the **Data Manager** interface and click on the **Select** button to display the **Patient information** interface. Then click on the **OK** button, the system will sample ECG data of the patient.



8.5 Merging Examination Records

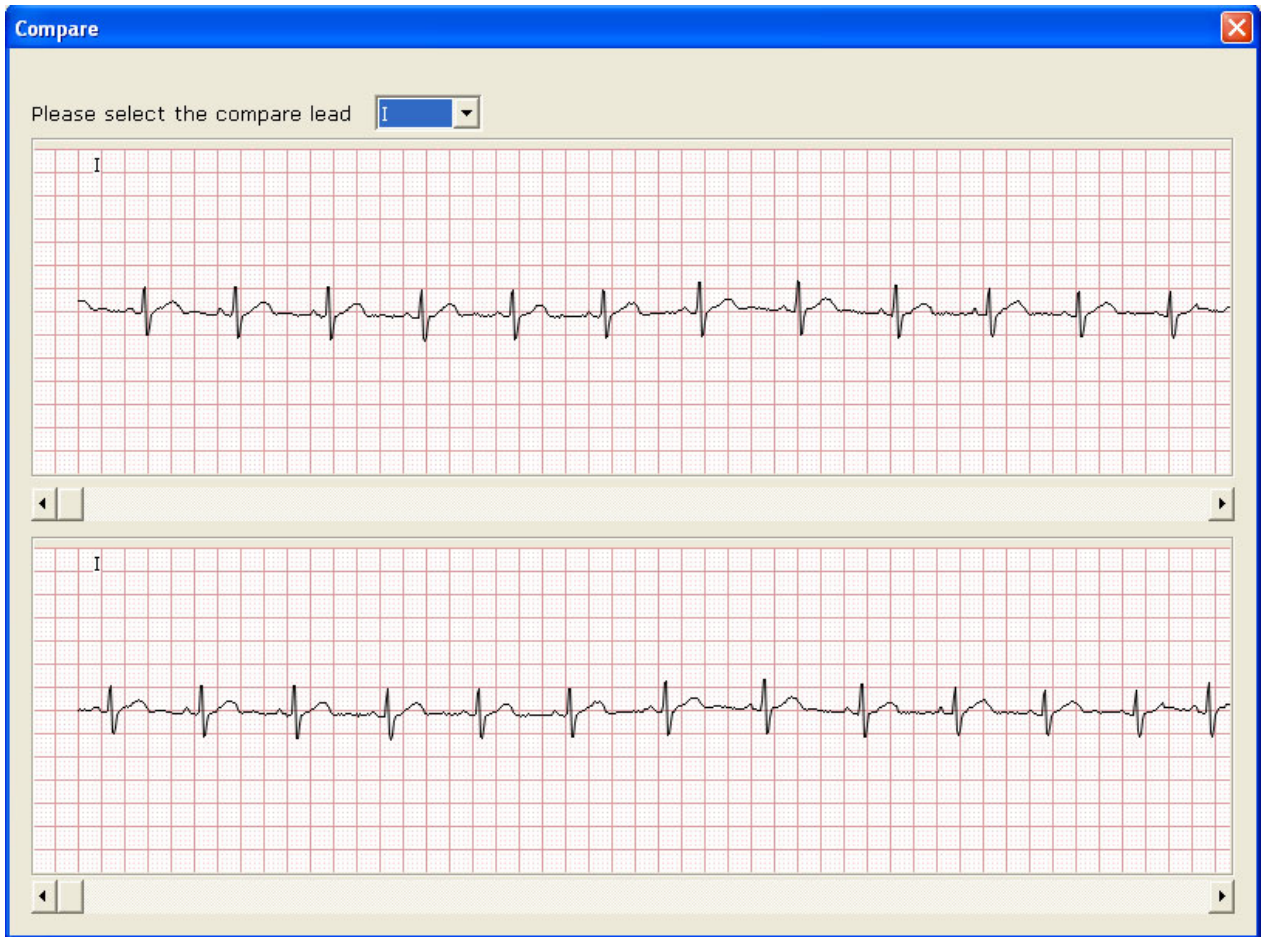
Click on an examination record in the examination record list on the **Data Manager** interface, and click on the **Merge/Assign** button to display the **Patient information** interface. Input a patient ID and click on the **OK** button to assign the examination record selected to this patient.

8.6 Comparing Two Examination Records

Press the **Ctrl** button on the keyboard and select two examination records, and then click on the **Compare** button to display the **Compare** interface.

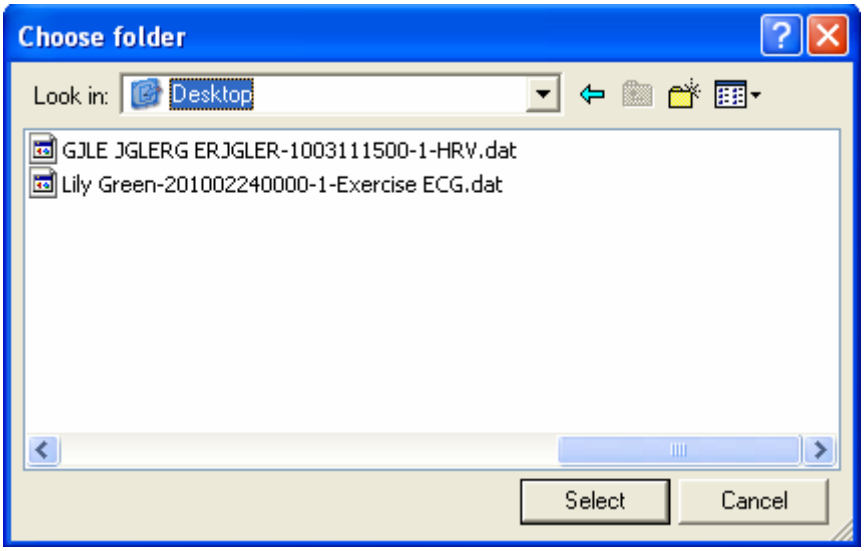
Note: Please select two records with the same examination item!

You can select the lead to be compared from the lead pull-down list. Then the waves of the selected lead of the two examination records will be displayed on the interface. You can drag the scroll bar on the bottom to view all the waves of the selected lead.

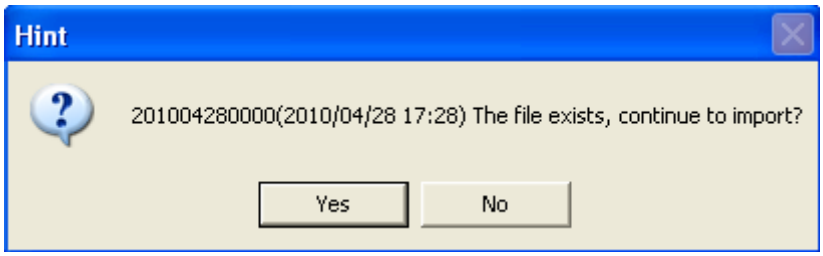


8.7 Importing ECG Data into the Data Manager Interface

Click on the **Import** button on the **Data Manager** interface (Figure 8-1) to open the following window. Select the data to be imported and click on the **Select** button to import the data into the **Data Manager** interface.



If the data to be imported exists on the **Data Manager** interface, the following hint will pop up.



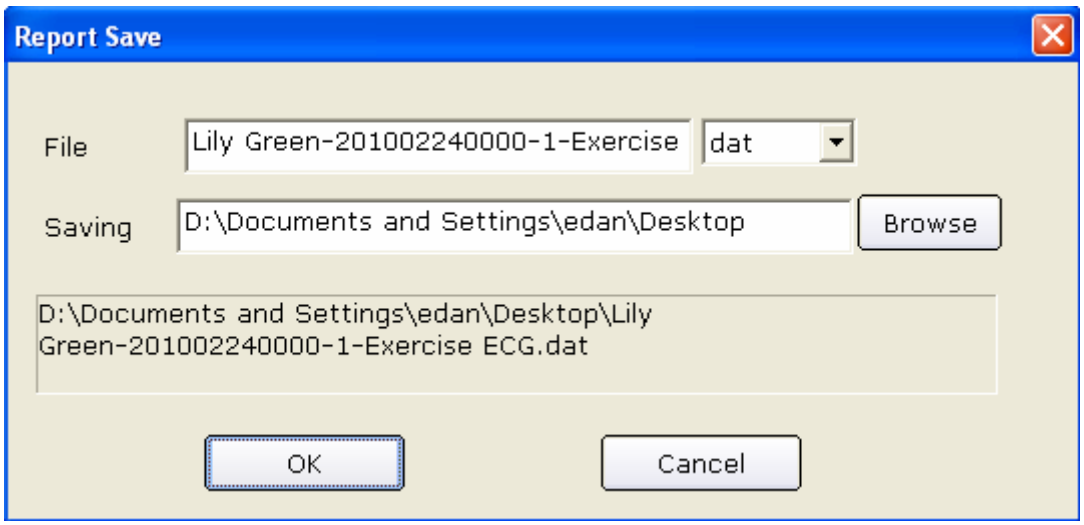
Click on the **Yes** button to import the data.

Click on the **No** button to cancel the operation.

Note: Only ECG data in DAT format can be imported.

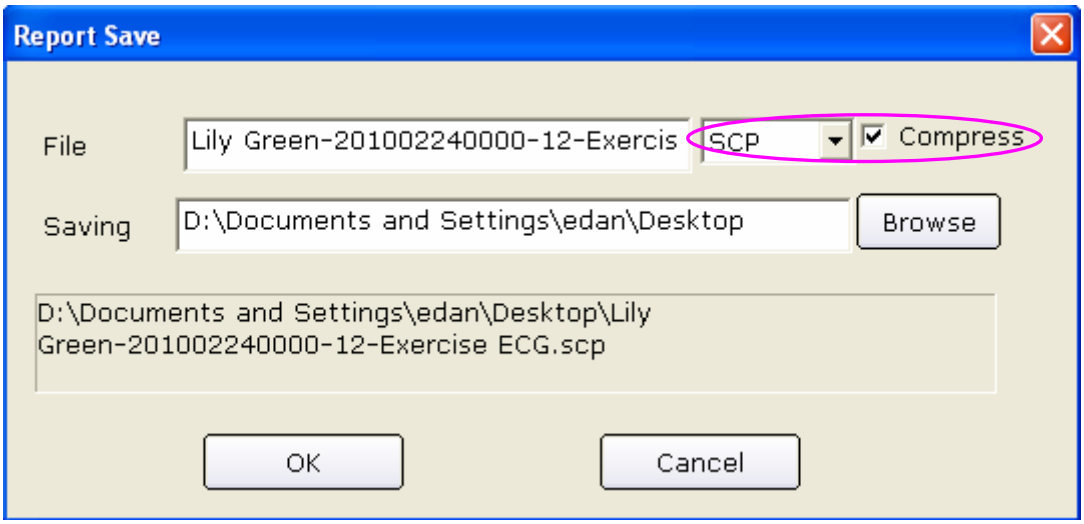
8.8 Exporting ECG Data from the Data Manager Interface

Select examination records and click on the **Export** button on the **Data Manager** interface (Figure 8-1) to open the following window. Assign the file name, saving path and export file format (SCP, FDA-XML, DICOM, dat), and then click on the **OK** button to export the data into the selected path. At the same time, the patient information of these records will be exported.



When the export is successful, the hint information will be displayed.

If you select **SCP** and **Compress**, the compressed SCP file will be exported.



Note: Only if the export file format is set to **SCP**, can the **Compress** check box be displayed.

8.9 Viewing an Examination Record

Click on a patient record in the patient information list, and then all the records of the patient will be displayed in the examination record list.

Select **All records** and all the examination records will be displayed in the examination record list.

Double-click on an examination record in the examination record list on the **Data Manager** interface (Figure 8-1). If it is a normal ECG record, the normal ECG analysis interface will pop up. If it is an HRV record, the HRV analysis interface will pop up. Then you can do the corresponding operation to the examination record. For more information about the operation, please refer to Section 6.6, “Analyzing ECG Data” and Section 7.9, “About Analysis Interface”.

Chapter 9 Configuring the System

Click on the **System Setting** button on the initial interface (Figure 6-1) to open the **System Setting** interface.

There are six tabs on the **System Setting** interface: **Basic Information**, **Sample Setting**, **Device**, **Print Setting**, **Others** and **GDT**.

After you modify some information on the **System Setting** interface,

1. Click on the **OK** button to save these modifications and exit.

2. Or click on the **Cancel** button to cancel these modifications and exit.

9.1 Basic Information Setup

Click on the **Basic Information** tab on the **System Setting** interface to display the basic information setup interface.

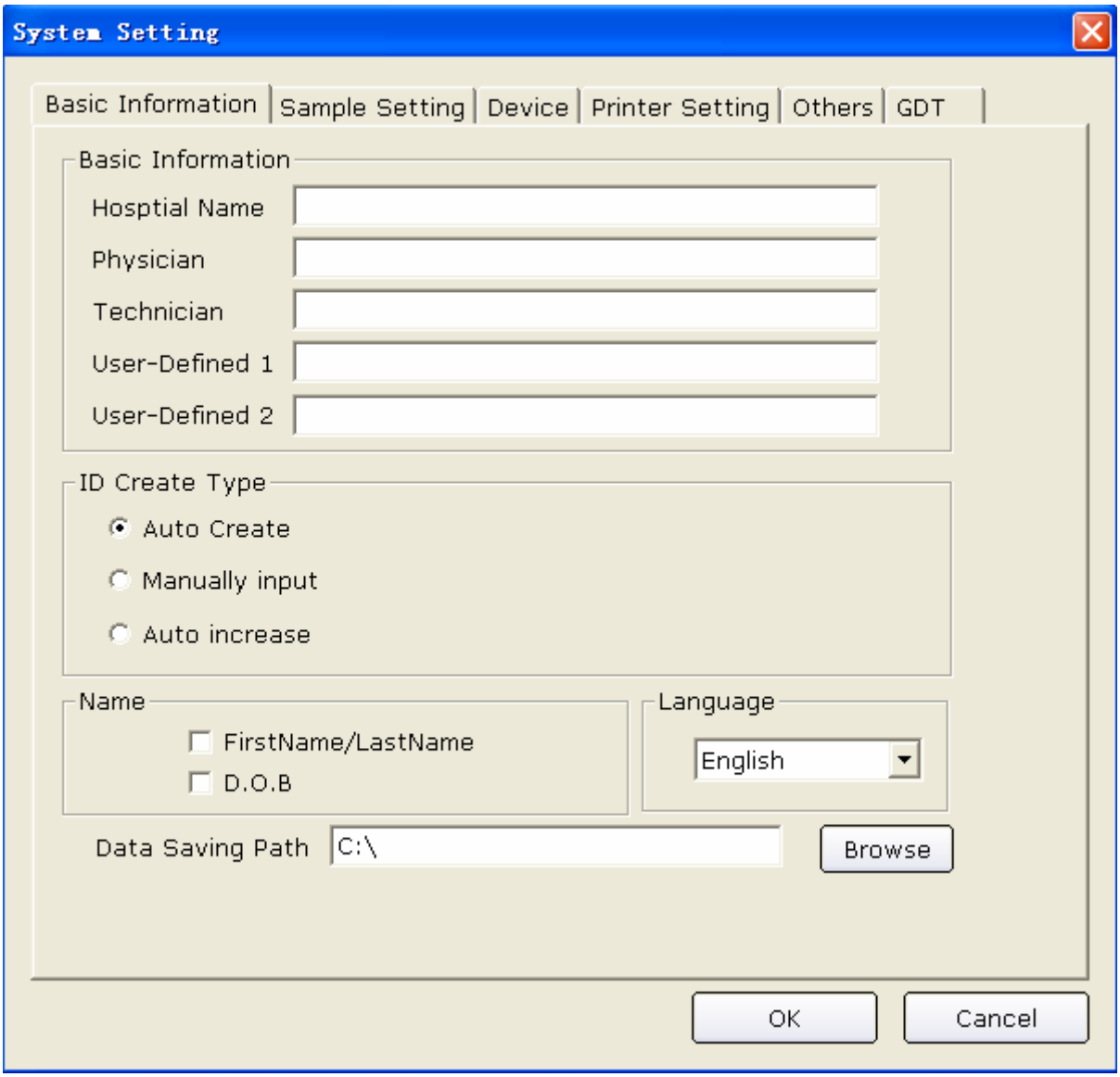


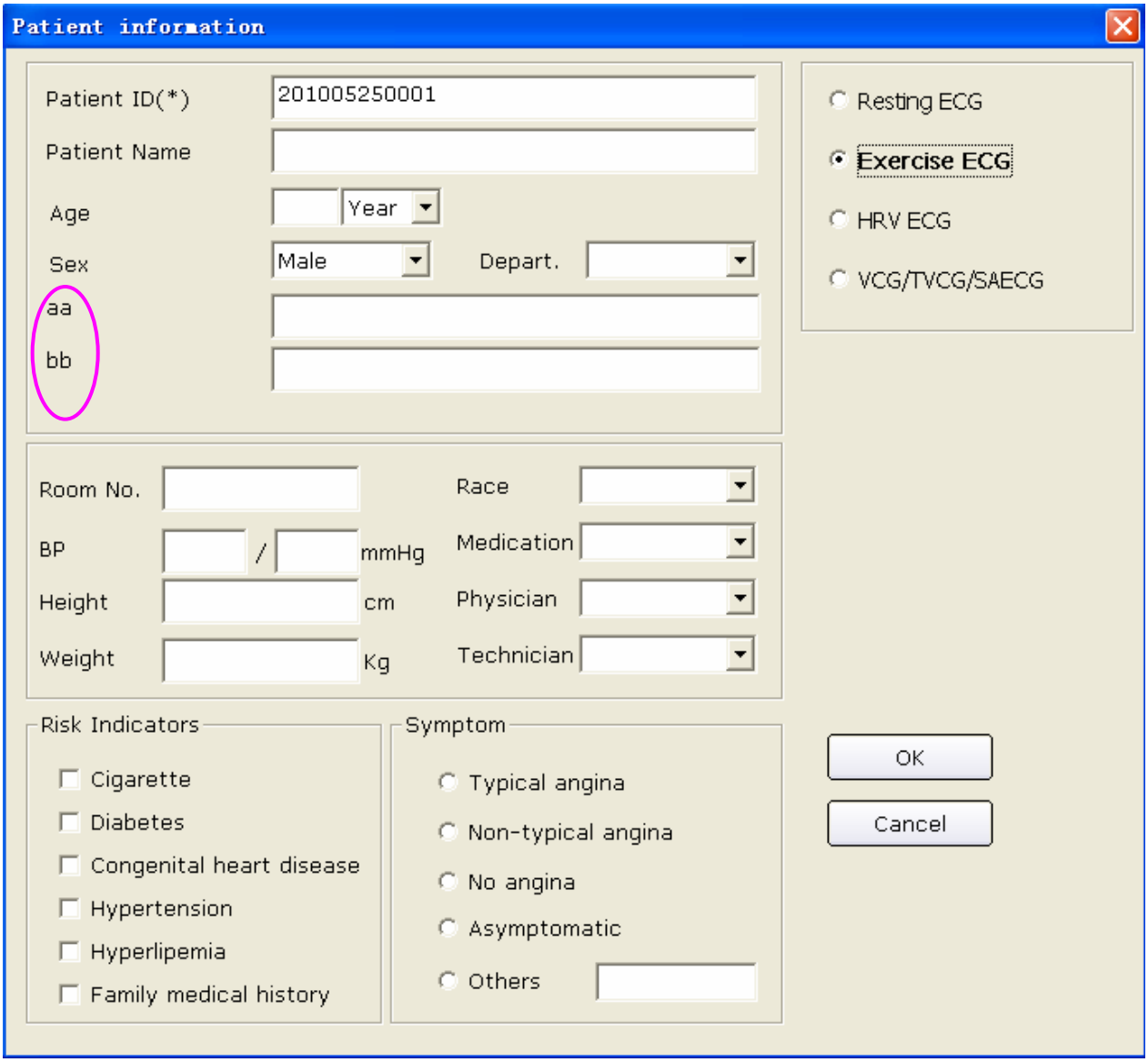
Figure 9-1 Basic Information Setup Interface

9.1.1 Setting Basic Information

Enter information in the **Hospital Name**, **Physician**, **Technician**, **User-Defined 1** or **User-Defined 2** textbox on the basic information setup interface (Figure 9-1).

When you fill in the **User-Defined 1/2** textbox, the corresponding items on the **Patient information** interface will change into what is filled.

For example, when you enter **aa** in the **User-Defined 1** textbox, and enter **bb** in the **User-Defined 2** textbox on the basic information setup interface (Figure 9-1), the corresponding items on the **Patient information** interface will be **aa** and **bb** respectively.



Note: Click on the **New Patient** button on the initial interface to open the **Patient information** interface as the above figure shows.

9.1.2 Setting ID Mode

Set **ID Create Type** to **Auto Create**, **Manually input** or **Auto increase**.

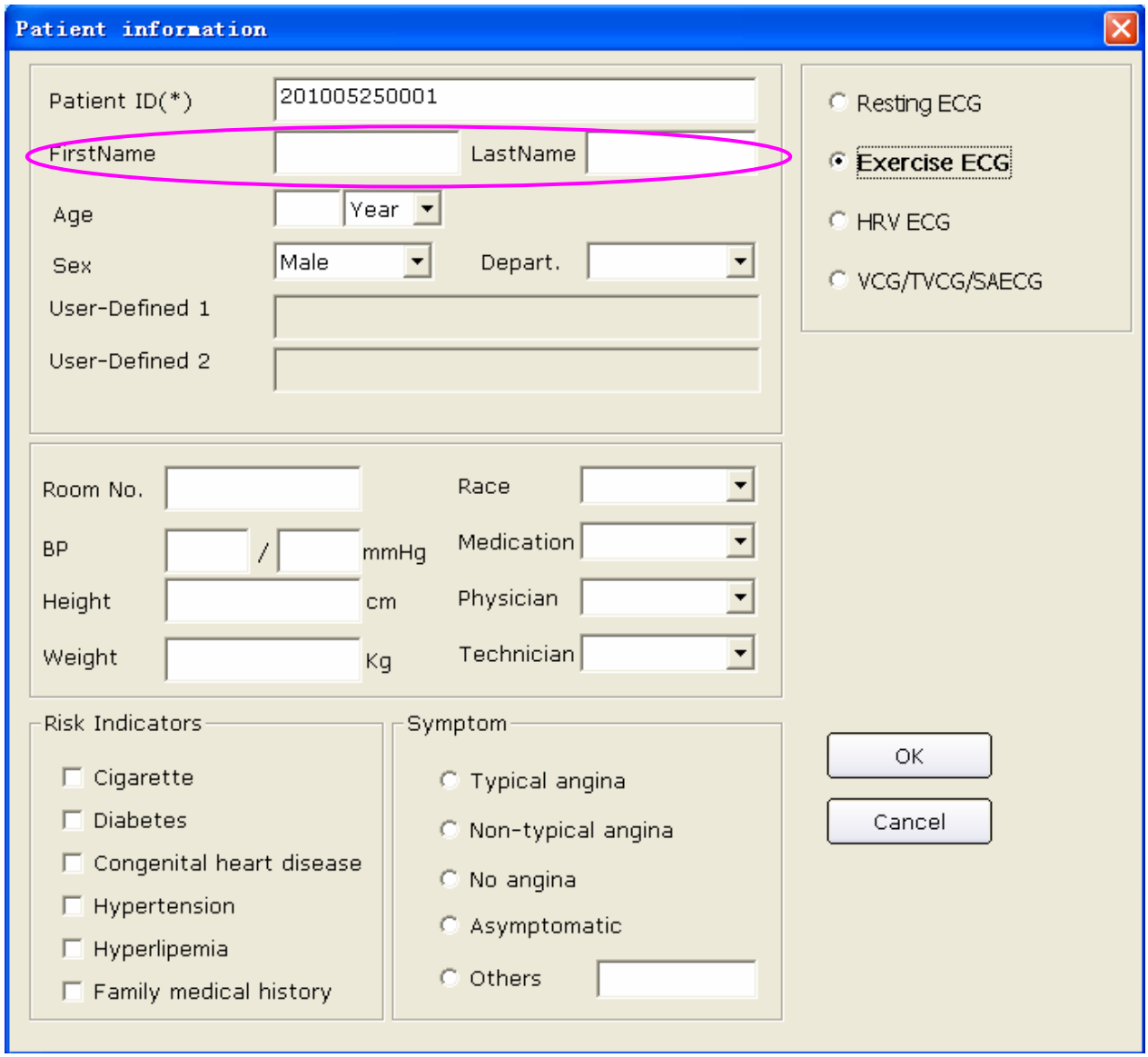
When **ID Create Type** is set to **Auto Create**, the patient ID can be automatically generated according to the examination date.

When **ID Create Type** is set to **Manually input**, you should enter the patient ID manually on the **Patient information** interface.

When **ID Create Type** is set to **Auto increase**, the patient ID can be increased by one automatically.

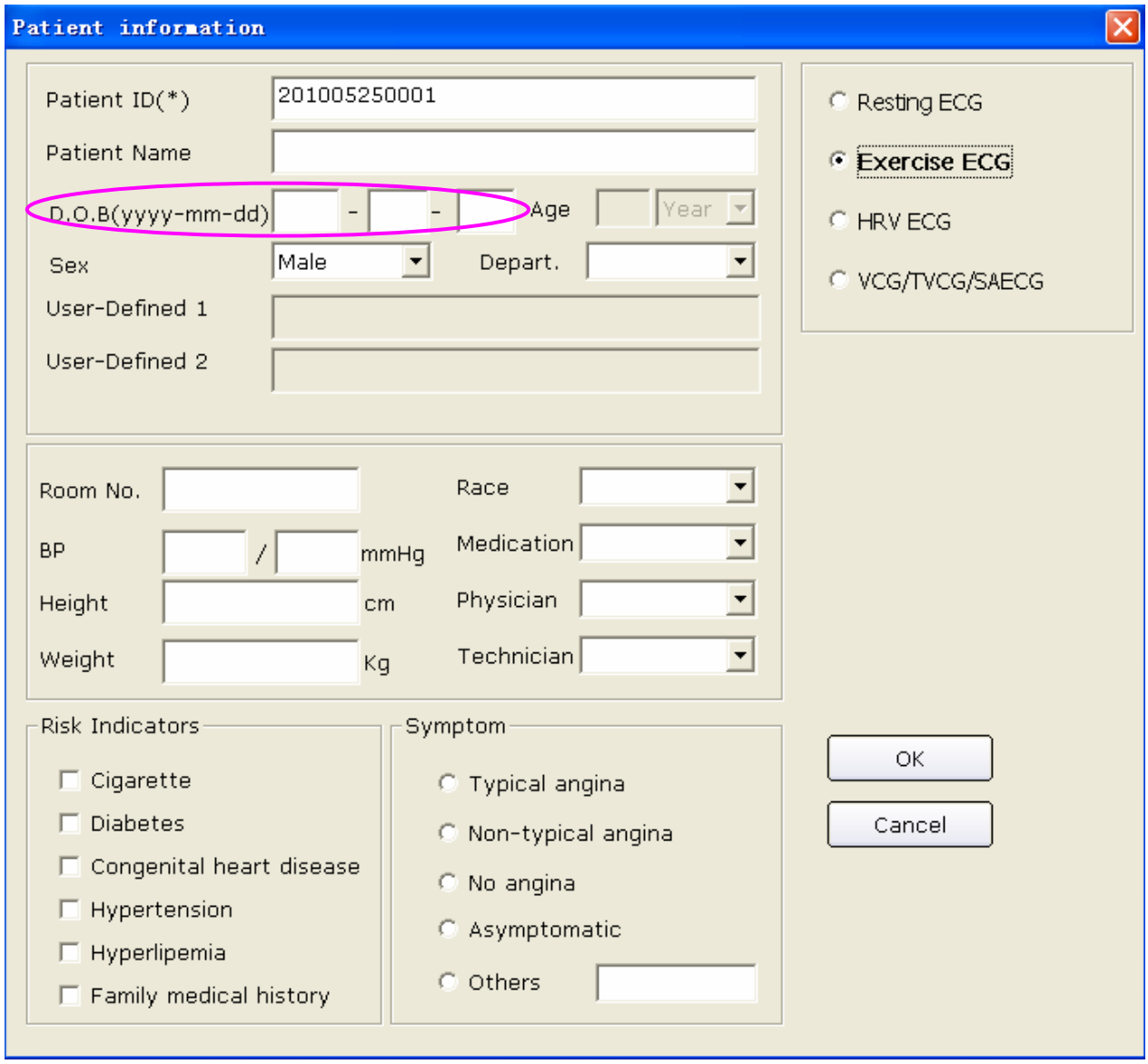
9.1.3 Setting Name Mode

If you select **First Name/Last Name**, the **Patient Name** textbox on the **Patient information** interface will change into the **First Name** and **Last Name** textboxes.



9.1.4 Selecting D.O.B

If you select **D.O.B**, the D.O.B textbox appears on the **Patient information** interface, and the **Age** textbox becomes unavailable.



9.1.5 Setting Language

You can set the language to **Chinese** or **English**.

Note: To validate the language setup, after setting, you should exit the system and open it again.

9.1.6 Specifying the Storage Path of the ECG Data

Click on the **Browse** button on the basic information setup interface (Figure 9-1) to assign the storage path.

9.2 Sample Setup

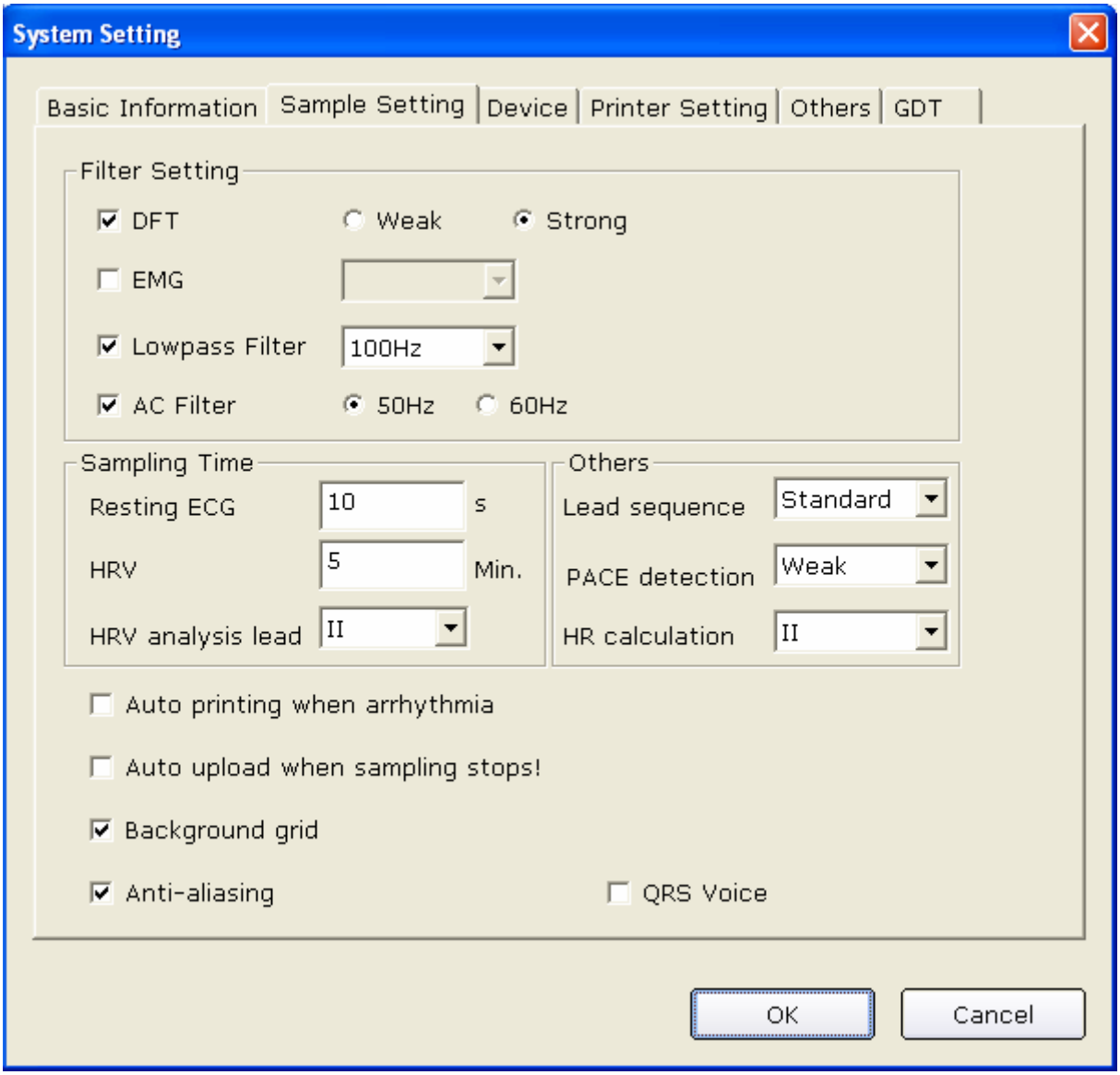
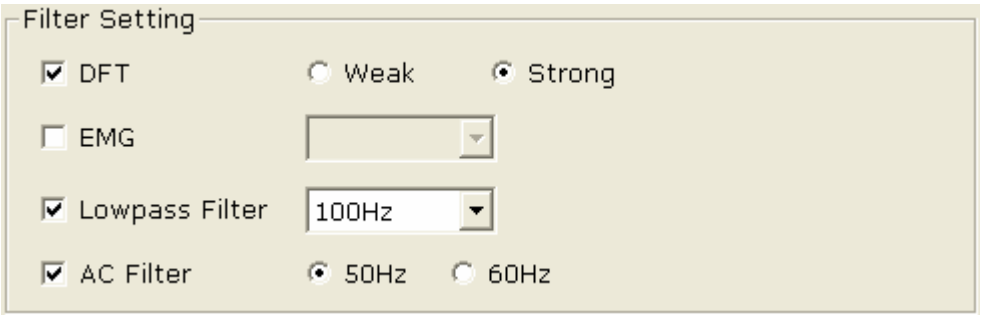


Figure 9-2 Sample Setup Interface

9.2.1 Setting Filter



Set filters on the sample setup interface (Figure 9-2).

DFT Filter

DFT filter greatly reduces the baseline fluctuations without affecting ECG signals. There are two options: **Weak** and **Strong**.

Note: If DFT filter is set to **Strong**, the ECG data displayed on the screen is 0.85 seconds later than the real-time ECG data; if DFT filter is set to **Weak**, the ECG data displayed on the screen is 1.8 seconds later than the real-time ECG data.

EMG Filter

EMG filter suppresses the disturbance caused by strong muscle tremor. The cutoff frequency can be set to **25Hz**, **35Hz**, or **45Hz**.

Lowpass Filter

Lowpass filter restricts the bandwidth of input signals. The cutoff frequency can be set to **75Hz**, **100Hz** or **150Hz**. All the input signals whose frequency is higher than the setting cutoff frequency will be attenuated.

AC Filter

AC filter suppresses AC interference without attenuating or distorting ECG signals. There are two options: **50Hz** and **60Hz**.

9.2.2 Setting Sampling Time

You can enter the normal ECG sampling time manually. The range is 0~10 min.
You can enter the HRV sampling time manually. The range is 1~15min.
You can set the HRV analysis lead to one of the 12 standard leads: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, or V6.

9.2.3 Setting Lead Sequence

You can set **Lead sequence** to **Standard** or **Cabrera**, and the lead groups are displayed or printed in the corresponding sequence listed in the following table.

Lead Sequence

Lead Sequence	Lead group 1	Lead group 2	Lead group 3	Lead group 4
Standard	I, II, III	aVR, aVL, aVF	V1, V2, V3	V4, V5, V6
Cabrera	aVL, I, -aVR	II, aVF, III	V1, V2, V3	V4, V5, V6

9.2.4 Setting Pacemaker Detection

When **PACE detection** is set to **Strong**, the pacemaker signals are easy to be detected.

When **PACE detection** is set to **Weak**, the pacemaker signals are not easy to be detected.

9.2.5 Setting HR Calculation Lead

You can set the **HR calculation** to one of the 12 standard leads: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, or V6.

9.2.6 Selecting Auto Printing When Detecting Arrhythmia

When **Auto printing when arrhythmia** is selected, if Arrhythmia ECG data, including Ventricular Tachycardia, 5>PVCS>=3, Paired PVCS, Bigeminy, Trigeminy, R ON T, single PVC and Missed Beat, is detected during the sampling course, printing will be triggered automatically.

9.2.7 Setting Auto Upload When Stopping Sampling

When **Auto upload when sampling stops!** is selected, the date will be uploaded to ENS after sampling is stopped.

9.2.8 Setting Background Grid

Select **Background Grid,** the grid on the background of the ECG sampling interface will be displayed.
Deselect **Background Grid**, the grid on the background of the ECG sampling interface will not be displayed.

9.2.9 Setting Anti-aliasing

Select **Anti-aliasing,** the system will automatically make the waveform smooth.
Deselect **Anti-aliasing**, the system will not make the waveform smooth.

9.2.10 Selecting QRS Voice

If you select **QRS Voice**, there will be a beep when an R wave is detected.

9.3 Device Setup

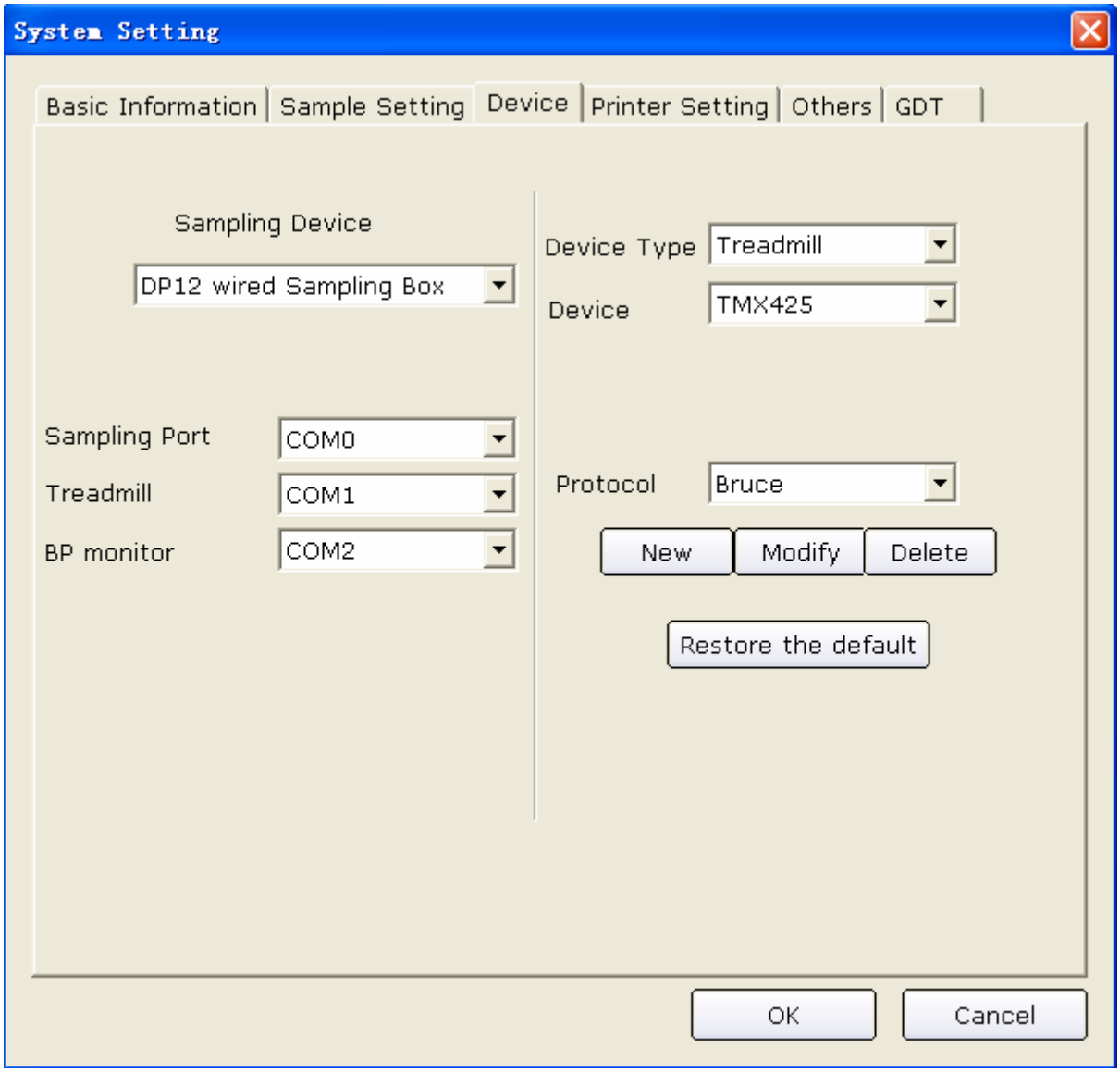
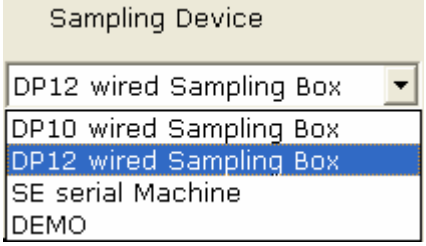


Figure 9-3 Device Setup Interface

9.3.1 Setting Sampling Device

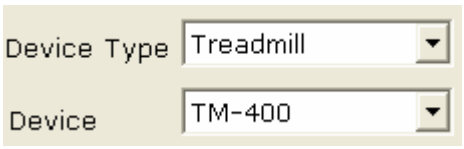
Select a sample device from the **Sampling Device** pull-down list



on the device setup interface (Figure 9-3).

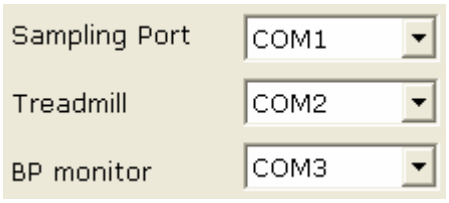
9.3.2 Setting Device Type/Mode

Select a device type/mode from the **Device Type/Device** pull-down list



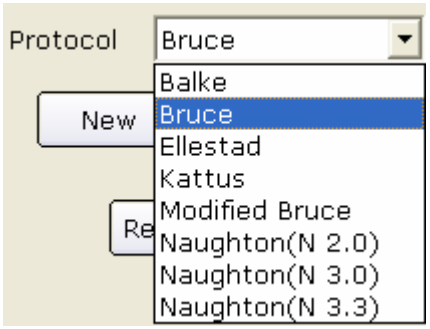
on the device setup interface (Figure 9-3).

9.3.3 Setting COM Port of Sample/Treadmill/BP Monitor



Set COM port of sampling/treadmill/BP monitor in on the device setup interface (Figure 9-3). To guarantee the system's proper operation, one of the preconditions is to ensure that the connection between the peripheral equipment and the PC accords with the setup in the software. For example, if you set the treadmill port to **COM2** on the device setup interface, you should connect the treadmill to COM2 of the PC; if you set the BP monitor port to **COM1** on the device setup interface, you should connect the BP monitor to COM1 of the PC.

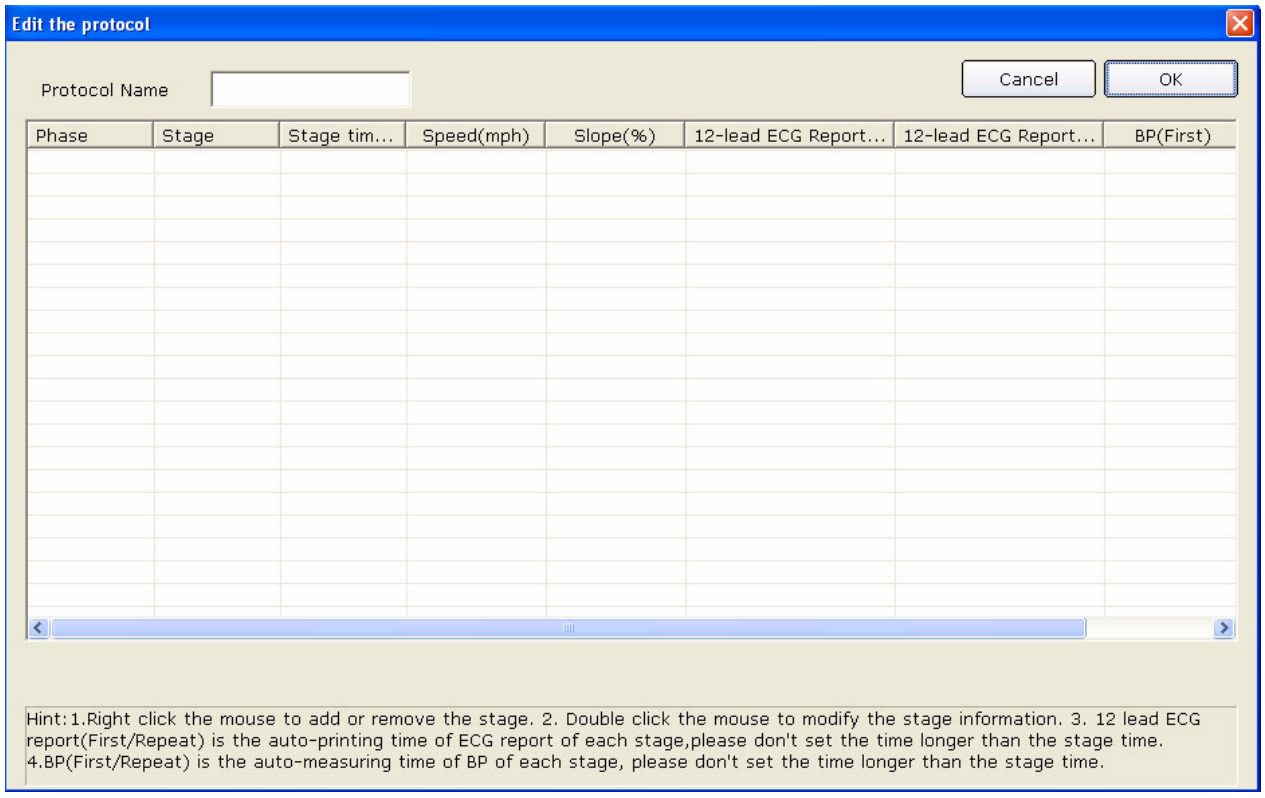
9.3.4 Setting a Protocol



Select a protocol from the **Protocol** pull-down list on the device setup interface (Figure 9-3). You can also add a new protocol or modify a protocol.

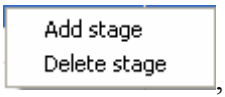
9.3.4.1 Creating a New Protocol

Click on the **New** button on the device setup interface (Figure 9-3) to enter the **Edit the protocol** interface.


Edit the protocol
Protocol Name
Cancel
OK
Phase
Stage
Stage tim...
Speed(mph)
Slope(%)
12-lead ECG Report...
12-lead ECG Report...
BP(First)
Hint: 1.Right click the mouse to add or remove the stage. 2. Double click the mouse to modify the stage information. 3. 12 lead ECG report(First/Repeat) is the auto-printing time of ECG report of each stage,please don't set the time longer than the stage time.
4.BP(First/Repeat) is the auto-measuring time of BP of each stage, please don't set the time longer than the stage time.

1. Enter the protocol name in the **Protocol Name** textbox

.

2. Right-click on the grid to display the menu 

, click on **Add Stage**, and enter information in the grid.

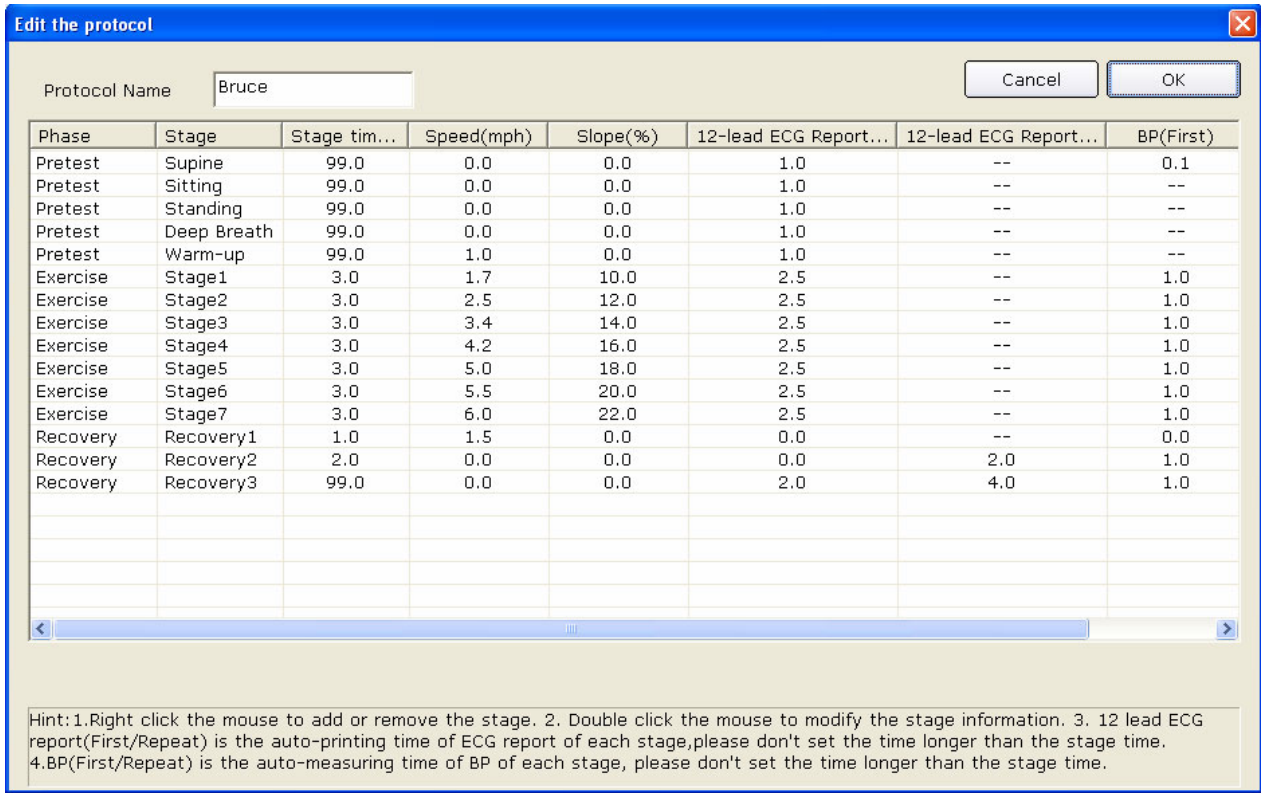
3. Set the auto printing time of 12-lead ECG reports in the **12-lead ECG Report (First)** and **12-lead ECG Report (Repeat)** columns.

4. Set the auto BP sampling time in the **BP (First)** or **BP (Repeat)** columns.

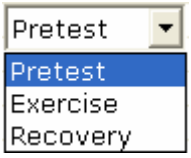
5. After entering all the information, click on the **OK** button.

9.3.4.2 Modifying a Protocol

1. Select a protocol from the **Protocol** pull-down list on the device setup interface (Figure 9-3). Then click on the **Modify** button to display the **Edit Protocol** interface.

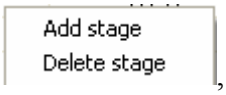

Edit the protocol
Protocol Name
Bruce
Cancel
OK
Hint: 1.Right click the mouse to add or remove the stage. 2. Double click the mouse to modify the stage information. 3. 12 lead ECG report(First/Repeat) is the auto-printing time of ECG report of each stage,please don't set the time longer than the stage time.
4.BP(First/Repeat) is the auto-measuring time of BP of each stage, please don't set the time longer than the stage time.

Phase	Stage	Stage tim...	Speed(mph)	Slope(%)	12-lead ECG Report...	12-lead ECG Report...	BP(First)
Pretest	Supine	99.0	0.0	0.0	1.0	--	0.1
Pretest	Sitting	99.0	0.0	0.0	1.0	--	--
Pretest	Standing	99.0	0.0	0.0	1.0	--	--
Pretest	Deep Breath	99.0	0.0	0.0	1.0	--	--
Pretest	Warm-up	99.0	1.0	0.0	1.0	--	--
Exercise	Stage1	3.0	1.7	10.0	2.5	--	1.0
Exercise	Stage2	3.0	2.5	12.0	2.5	--	1.0
Exercise	Stage3	3.0	3.4	14.0	2.5	--	1.0
Exercise	Stage4	3.0	4.2	16.0	2.5	--	1.0
Exercise	Stage5	3.0	5.0	18.0	2.5	--	1.0
Exercise	Stage6	3.0	5.5	20.0	2.5	--	1.0
Exercise	Stage7	3.0	6.0	22.0	2.5	--	1.0
Recovery	Recovery1	1.0	1.5	0.0	0.0	--	0.0
Recovery	Recovery2	2.0	0.0	0.0	0.0	2.0	1.0
Recovery	Recovery3	99.0	0.0	0.0	2.0	4.0	1.0

2. Double-click on an option of the phase row to be modified in the protocol list, and the pull-down list 

will be displayed. Select a phase and it will be displayed in the corresponding grid.

3. Double-click on the grid to be modified, input new information, and click on any other grid to save the information.

4. Right-click on the grid to display the menu 

, click on **Add Stage**, and enter information in the grid.

5. Set the auto printing time of 12-lead ECG reports in the **12-lead ECG Report (First)** and **12-lead ECG Report (Repeat)** columns.

6. Set the auto BP sampling time in the **BP (First)** or **BP (Repeat)** columns.

7. Click on the **OK** button to confirm, or click on the **Cancel** button to cancel modifications.

9.3.4.3 Deleting a Protocol

Select a protocol from the **Protocol** pull-down list on the device setup interface (Figure 9-3). Then click on the **Delete** button to delete the protocol.

9.3.4.4 Restoring the Factory Settings

Click on the **Restore the default** button to resume the factory settings.

9.4 Printer Setup

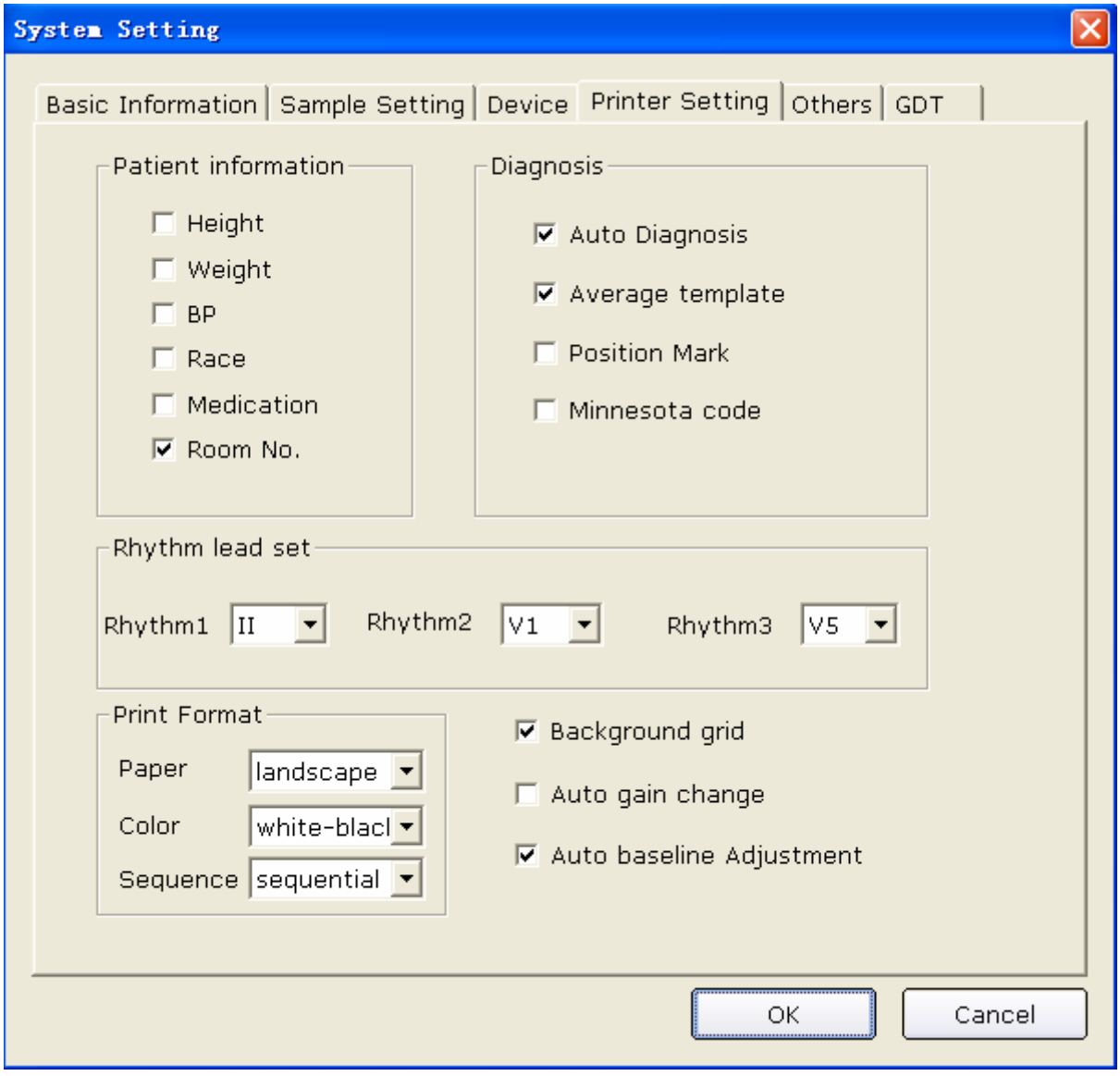


Figure 9-4 Printer Setting Interface

9.4.1 Choosing Patient Information to be Printed

The patient information is displayed on the preview interface and in the report printed out. It includes the height, weight, room number, BP, race, and medication which are optional.

9.4.2 Choosing Diagnosis Information to be Printed

The diagnosis information is displayed on the preview interface and in the report printed out.

Position Mark should be selected together with **Average template**, because the position mark is only used to mark the position of ECG waves in the average template. Select **Auto Diagnosis** to display diagnosis results on the preview interface and in the report printed out. Select **Minnesota code** to display Minnesota code.

9.4.3 Setting Rhythm Lead

The rhythm lead can be one of 12 standard leads: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, or V6.

When the printing mode is set to **3×4+1** or **6×2+1**, the rhythm lead selected in the **Rhythm1** list box will be printed out.

When the printing mode is set to **3×4+3**, 3 rhythm leads selected in the **Rhythm1**, **Rhythm2** and **Rhythm3** list boxes will be printed out.

9.4.4 Defining Printing Format

1. The paper form can be set to **landscape** or **portrait**.
2. The printing color can be set to **white-black** or **color.**

Note: If the printing color is set to color, but a black-and-white printer is used, the report printed will be illegible.

3. Select **Background grid**, and the background grid will be printed in the report.
   Deselect **Background grid**, and the background grid won't be printed in the report.
4. Select **Auto gain change**, and the gain will be changed automatically.
5. Select **Auto baseline change**, the baseline will be adjusted automatically.
6. Set **Sequence** to **sequential** or **synchronous**.

When **Sequence** is set to **sequential**, the lead group is printed one by one in a certain sequence. The start time of a lead group is just the end time of the previous lead group.

When **Sequence** is set to **synchronous**, all leads are printed simultaneously. The start time of each group is the same.

9.5 Other Setup

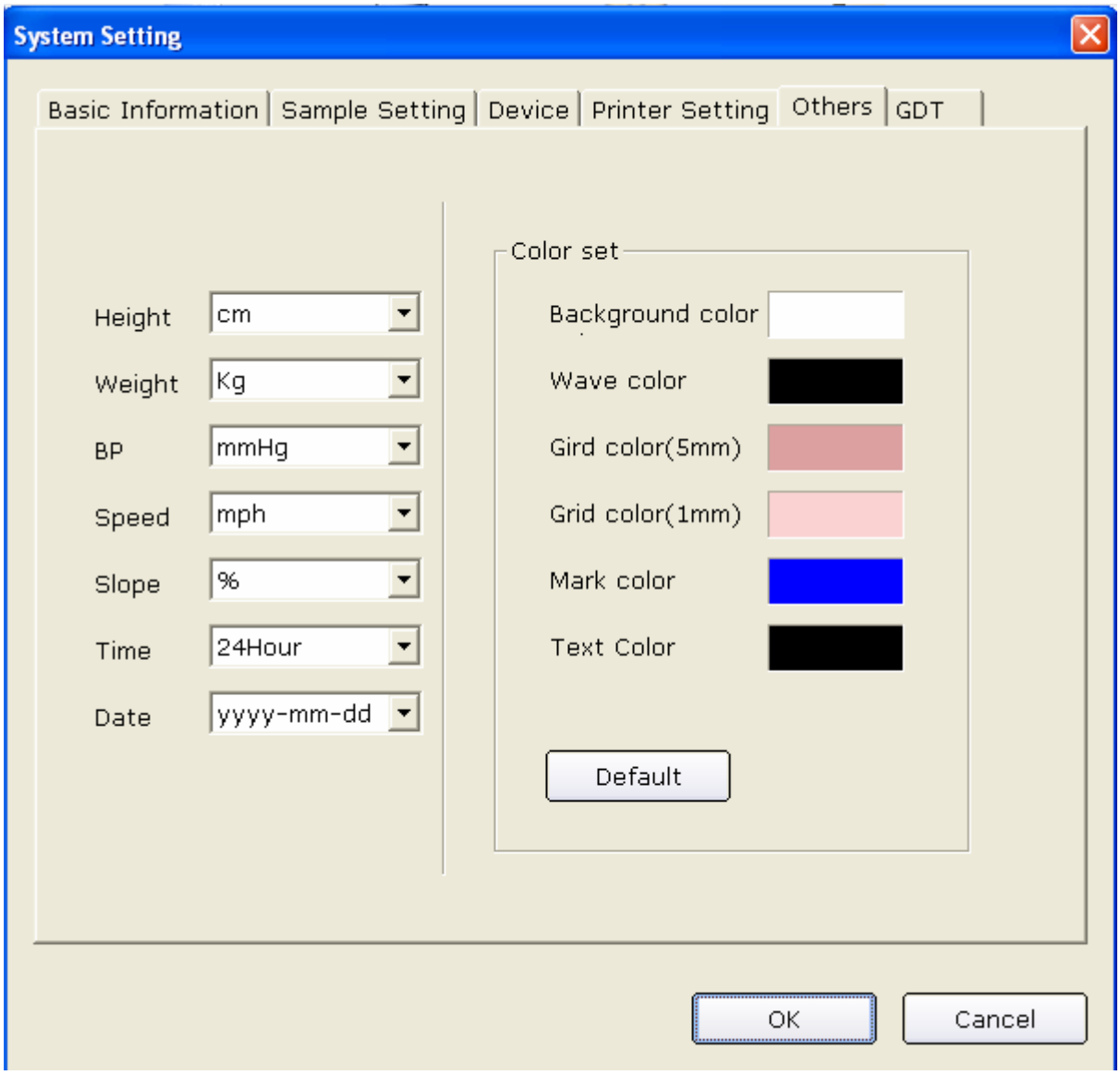


Figure 9-5 Other Setup Interface

Set the height unit to **cm**, **inch** or **mm**.

Set the weight unit to **Kg, g** or **Pound**.

Set the BP unit to **KPa** or **mmHg**.

Set the speed unit to **Km/h** or **mph**.

Set the grade unit to **%** or **degree**.

Set the time mode to **24Hour** or **12Hour**.

Set the date mode to **mm-dd-yyyy, dd-mm-yyyy or yyyy-mm-dd.**

Set the color of the background, waves, grid (5mm), grid (1mm), mark and text. If you want to change a color, double-click on the color block to display the **Color** interface, and then you can select your favorite color.

Click on the **Default** button to restore the default colors.

9.6 GDT Setup

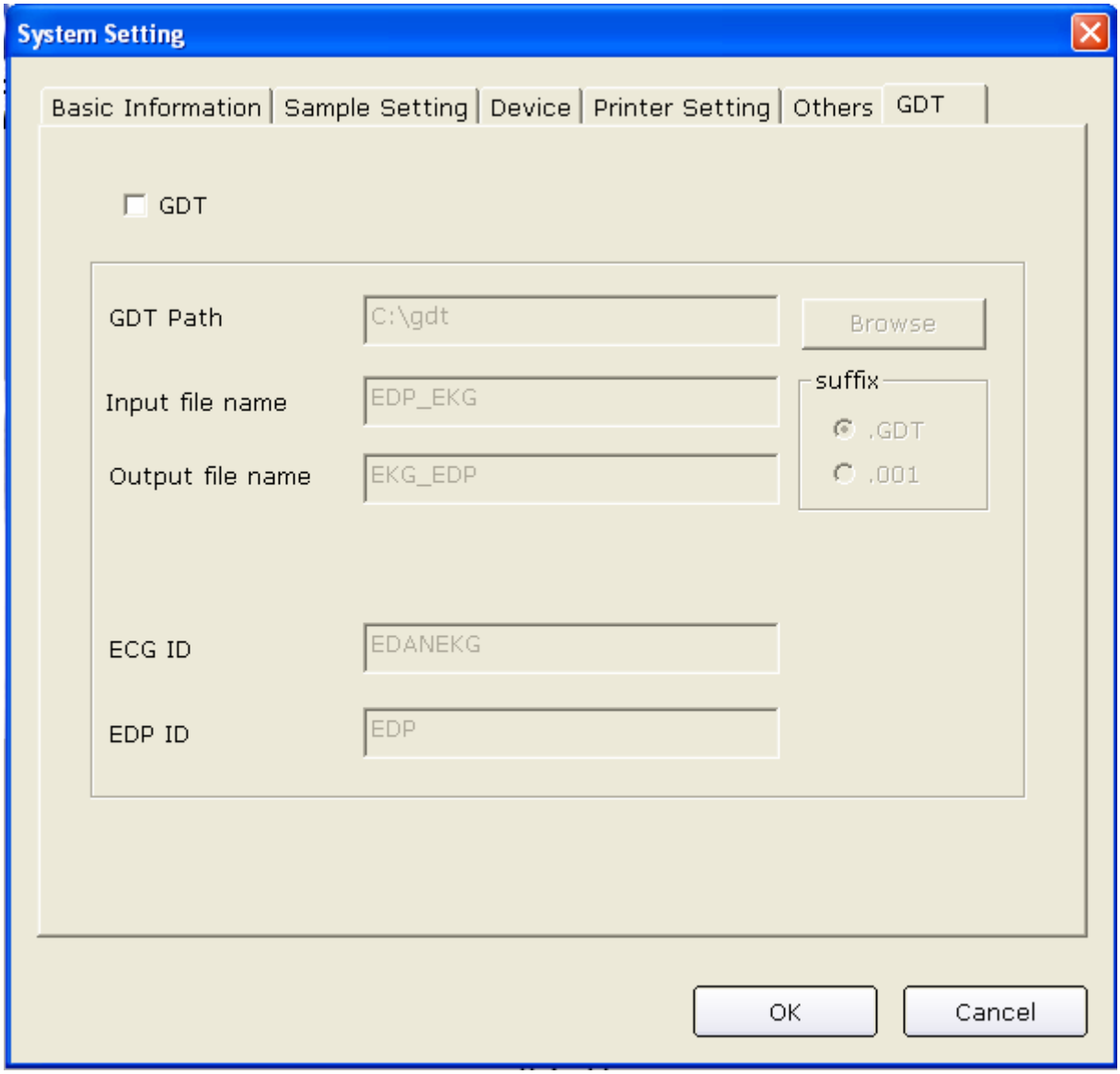


Figure 9-6 GDT Setup Interface

Select **On GDT** to enable GDT features.

Click on the **Browse** button, and then appoint the path to exchange files with EDP.

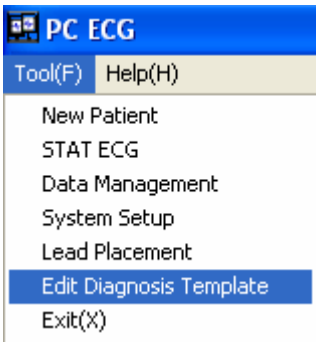
Fill in the **Input file name** textbox to set command file name assigned by EDP to the PC ECG system.

Fill in the **Output file name** textbox to set data file name that is used by the PC ECG system to transmit the result data to EDP.

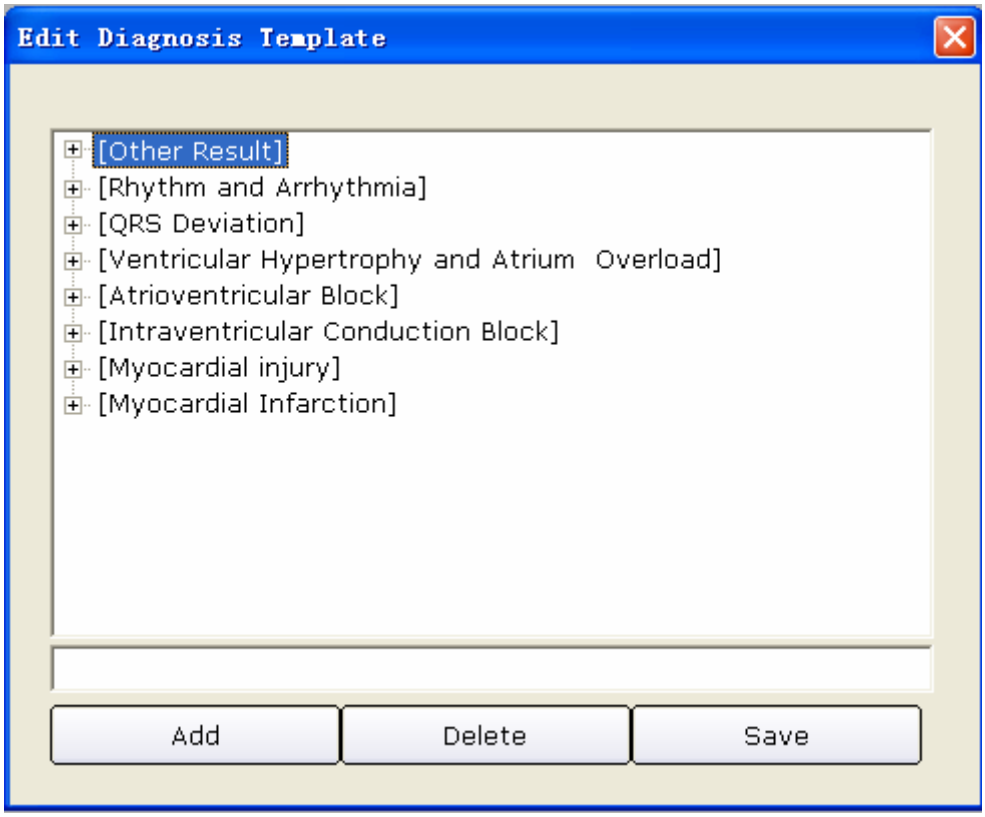
Enter ECG ID to set GDT ID assigned to the system which will be entered in field 8315 or 8316 in the GDT protocol.

Enter EDP ID to set GDT ID of the EDP system which will be entered in field 8315 or 8316 in the GDT protocol.

9.7 Modifying the Glossary



Click on **Edit Diagnosis Template** in the **Tool (F)** pull-down list on the initial interface (Figure 6-1), and then the **Edit Diagnosis Template** window appears.



1. Select an item, such as **Other Result**. Enter your own opinions in the bottom textbox, and then click on the **Add** button. The content entered will be added under **Other Result**.

2. Click on the diagnosis information required to be deleted, and then click on the **Delete** button to delete the selected information.

3. Click on the **Save** button to save these modifications.

Chapter 10 Hint Information

Hint information and the corresponding causes provided by the system are listed as follows.

Table 10-1 Hint Information and Causes

Hint Information	Causes
Lead off: X	Electrodes fall off the patient or the patient cable falls off the ECG sampling box.
It is pre-sampling now, please click on 'Start' to begin recording.	During the pre-sampling course
Can't find the sentinel!	The sentinel is not installed.
The sentinel setting is wrong!	The sentinel is set wrongly.
Hint: Please make sure the USB line has been connected. If possible, please re-connect it!	The USB cable is disconnected or the communication between the ECG sampling box and the serial port is interrupted. 1. Reconnect the ECG sampling box to the PC. 2. Click on the **Device** tab on the **System Setting** interface of the PC ECG system, and check whether the sampling device is set correctly.
Overload	The direct current offset voltage on an electrode is too high.
Fail to open the treadmill (ergometer) port! Please make sure the treadmill (ergometer) has been connected to the computer and the port setting is right	Fail to open the COM port which controls the treadmill/ergometer. Reconnect the treadmill/ergometer to the PC, and set the COM port correctly.
Fail to open the BP monitor port! Please make sure the BP monitor has been connected to the computer and the Port set is right!	Fail to open the COM port which controls the blood pressure. Reconnect the BP monitor to the PC, and set the COM port correctly.
The current HR has exceeded the target HR!	Current heart rate value exceeds the target heart rate value.
The diastolic BP has exceeded the normal range!	Diastolic blood pressure exceeds the normal BP range.
The systolic BP has exceeded the normal range!	Systolic blood pressure exceeds the normal BP range.
Sorry, Can not Connect to the DataBase!	MSDE 2000 or SQL Server 2005 Express is not started up.

Fail to create database!	The system fails to create database.
Communication error! Please check the USB cable!	The USB cable falls off the PC during the sampling process.

According to IEC/EN 60601-1-8, the characteristics of the visual alarm signals (hint information) are listed in Table 10-2.

Table 10-2 Characteristics of Visual Alarm Signals (Hint Information)

Alarm Category	Indicator Color	Flashing Frequency	Duty Cycle
LOW	Yellow	Constant (on)	100%

Chapter 11 Cleaning and Maintenance

CAUTION

Turn off the system power and drag the power cable out from the socket before cleaning or disinfection.

11.1 Cleaning and Maintaining the Treadmill

Daily Cleaning and Maintenance

1. Wipe the treadmill with a clean soft cloth to remove dust, moisture and sweat stain.
2. Wipe the handrail of the treadmill with a clean soft cloth damped in non-caustic neutral detergent.
3. Do not pour or spray detergent onto the treadmill directly.

Weekly Cleaning and Maintenance

1. Clean dust around the treadmill with a dust-collector.
2. Check whether the emergency stop switch is valid.
3. Check the tightness degree of the running belt.

Semiyearly Cleaning and Maintenance

1. Lubricate the screws.
2. Valuate the state of the treadmill.

11.2 Cleaning and Maintaining the Patient Cable and Reusable Electrodes

WARNING

Failure on the part of the responsible individual hospital or institution employing this equipment to implement a satisfactory maintenance schedule may cause undue equipment failures and possible health hazards.

- Clean the patient cable with a clean soft cloth. Do not use the detergent containing alcohol to clean the patient cable.
- Integrity of the patient cable, including the main cable and lead wires, should be checked regularly. Make sure that it is conductible.
- Do not drag or twist the patient cable with excessive stress while using it. Hold the connector plugs instead of the cable when connecting or disconnecting the patient

cable.

- ♦ Align the patient cable to avoid twisting, knotting or crooking at a closed angle while using it.
- ♦ Store the lead wires in a big wheel.
- ♦ Once damage or aging of the patient cable is found, replace it with a new one immediately.

Remove the remainder gel from the electrodes with a clean soft cloth first. Take suction bulbs and metal cups of chest electrodes apart, and take clamps and metal parts of limb electrodes apart. Clean them in warm water and make sure that there is no remainder gel. Dry the electrodes with a clean dry cloth or air dry naturally.

CAUTION

1. The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal.
2. The disposable electrodes can only be used for one time.

11.3 Disinfection

To avoid permanent damage to the equipment, disinfection can be performed only when it is considered as necessary according to your hospital's regulations.

Before disinfection, clean the equipment first. Then wipe the surfaces of the unit and the patient cable with hospital standard disinfectant.

CAUTION

Do not use chloric disinfectant such as chloride, sodium hypochlorite etc.

Chapter 12 Accessories

WARNING

Only the patient cable and other accessories supplied by the manufacturer can be used. Or else, the performance and electric shock protection can not be guaranteed.

Table 12-1 Standard Accessory List

Accessory	Part Number
DP12 ECG Sampling Box	02.01.210039
Softdog / USB	01.18.047225
Patient Cable / European Standard (for resting ECG test)	01.57.106902
Patient Cable / American Standard (for resting ECG test)	01.57.107048
Limb Electrode	01.57.040162
Chest Electrode	01.57.040163
Resting ECG External USB Cable	01.13.036134
Portable Bag	11.56.078136

Table 12-2 Optional Accessory List

Accessory	Part Number
Softdog / USB	01.18.047229
Patient Cable (for exercise ECG)	01.57.109850
ECG Electrode (for exercise ECG)	01.57.040171
Disposable Frosting Film for Skin Preparation	01.57.107418
MSB1212 Disposable Electrode	01.57.040171
Exercise ECG External USB Cable	01.13.036135
Computer Lenovo, Qitian M6900	11.18.052208
Snap/Banana Socket Adapter	01.13.107449

Chapter 13 Warranty and Service Policy

13.1 Warranty

EDAN warrants that EDAN's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period. The warranty period begins on the date the products are shipped to distributors.

The warranty is void in case of:

a) damage caused by handling during shipping.

b) subsequent damage caused by improper use or maintenance.

c) damage caused by alteration or repair by anyone not authorized by EDAN.

d) damage caused by accidents.

e) replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, EDAN will, at its discretion, repair or replace the defective part(s) free of charge. EDAN will not provide a substitute product for use when the defective product is being repaired.

13.2 Service Policy

All repairs on products must be performed or approved by EDAN. Unauthorized repairs will void the warranty. In addition, whether or not covered under warranty, any product repair shall be exclusively be performed by EDAN certified service personnel.

If the product fails to function properly or if you need assistance, service, or spare parts, contact EDAN's service center. A representative will assist you troubleshooting the problem and will make every effort to solve it over the phone or Email, avoiding potential unnecessary returns.

In case a return can not be avoided, the representative will record all necessary information and will provide a Return Material Authorization (RMA) form that includes the appropriate return address and instructions. An RMA form must be obtained prior to any return.

Freight policy:

Under warranty: the service claimer is responsible for freight & insurance charges when a return is shipped to EDAN for service including custom charges. EDAN is responsible for freight, insurance & custom charges from EDAN to service claimer.

Out of warranty: the service claimer is responsible for any freight, insurance & custom charges for product.

Contact information:

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Alternatively, you can send an email to EDAN service department at: support@edan.com.cn.

Chapter 14 Recommended Optional Accessories

Treadmill:

Model: TM-400
Manufacturer: Edan Inc. China
CE marking

Model: Valiant
Manufacturer: Lode B.V. The Nettherlands
CE marking

Model: TMX425, TMX425C, TMX425CP
Manufacturer: Full Vision Inc. USA
CE marking

Model: mercury med 4.0, mercury 4.0
Manufacturer: h/p/cosmos sports & medical gmbh Germany
CE marking

Ergometer:

Model: sana bike 120F, sana bike 150F, sana 250F
Manufacturer: ergosana gmbh Germany
CE marking

Model: ergoselect 100P/100K, ergoselect 200P/200K
Manufacturer: ergoline gmbh Germany
CE marking

Model: Corival
Manufacturer: Lode B.V. The Nettherlands
CE marking

STRESS BP:

Model: Tango+
Manufacturer: SunTech Medical Inc. USA
CE Certificate and FDA 510(k) clearance

Isolating Transformer:

Model: ES710
Manufacturer: BenDer Inc. Deutschland

Electrical Outlet:

Power Consumption: no less than 4500VA
Special use for medical equipment

Printer:

Model: HP2035, HP5568
Manufacturer: HP Company, USA

Model: CANON3500, CANON1800
Manufacturer: CANON Company, Japan

WARNING

1. The electrical outlet and the isolating transformer shall only be used for supplying power to the part of the system.

2. It will harm the wall outlet to connect the non-medical electrical equipment of the PC ECG system directly to the wall outlet, because the non-medical electrical equipment of the system is intended to be powered by using the electrical outlet and the isolating transformer.

3. An additional multiple portable socket-outlet or extension cord shall not be connected to the system.

4. The electrical outlet and the isolating transformer shall not be placed on the floor.

Appendix 1 Technical Specifications

A1.1 Safety Specifications

Comply with:		IEC 60601-1: 1988+A1+A2, EN 60601-1:1990+A1+A2, IEC/EN60601-1-2: 2001+A1, IEC/EN60601-2-25, ANSI/AAMI EC11, IEC/EN60601-2-51
Anti-electric-shock type:		Class II
Anti-electric-shock degree:		Type CF
Degree of protection against harmful ingress of water:		Ordinary equipment (Sealed equipment without liquid proof)
Disinfection/sterilization method:		Refer to the user manual for details
Degree of safety of application in the presence of flammable gas:		Equipment not suitable for use in the presence of flammable gas
Working mode:		Continuous operation
EMC:		Group I, Class A
Patient Leakage Current:	NC	<10μA (AC) / <10μA (DC)
	SFC	<50μA (AC) / <50μA (DC)
Patient Auxiliary Current:	NC	<10μA (AC) / <10μA (DC)
	SFC	<50μA (AC) / <50μA (DC)

A1.2 Environment Specifications

	Transport & Storage	Working
Temperature:	-40ºC (-40ºF) ~ +55ºC (+131ºF)	+5ºC (+41ºF) ~ +40ºC (+104ºF)
Relative Humidity:	25%~93% Non-Condensing	25%~80% Non-Condensing
Atmospheric Pressure:	700hPa ~1060hPa	860hPa ~1060hPa

A1.3 Physical Specifications

Dimensions	148 mm (L) ×100 mm (W) × 40 mm (H) (5.8in×3.9in×1.6in)
Weight	Approx. 210g (0.44lbs)

A1.4 Power Supply Specifications

Power Supply:	PC	Operating Voltage: 110V-240V~
		Operating Frequency: 50 Hz/60 Hz
	ECG Sampling Box	DC 5V
		Input Power: 1 VA(MAX), 0.5 VA(MIN)

A1.5 Performance Specifications

Display	
Display Content	System name, Patient ID, Patient name Hear rate, Display mode, Printing mode Speed, Gain, Lowpass Filter Hint information ECG waves
Recording	
Recording Paper:	A4 recording paper
Paper Width:	210 mm (A4)
Paper Speed:	5 mm/s, 10 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s（±3%）
Record message:	Date, Time, Printing Speed, Filter, Symbol, Heart Rate, Patient ID, Sex, Age, Lead Mark, Lead Wave, Average Template Wave or Rhythm Lead Wave, Measurement Result and Interpretation Information Result (option) etc.
Channel:	3 / 6 / 12 channels, auto baseline adjustment
HR Recognition	
Technique:	Peak-peak detection
HR Range:	30 BPM ~300 BPM
Accuracy:	±1 BPM

Memory	
Memory:	Storage amount depends on PC machine
ECG Sampling Box Performance	
Leads Mode:	12 standard leads/ Cabrera leads
Acquisition Mode:	simultaneously 12 leads
Sample Frequency:	1000 Hz
A/D Resolution:	24 bits
Time Constant:	≥3.2 s
Frequency Response:	0.05 Hz ~ 150 Hz (-3 dB)
Gain:	2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV
Input Impedance:	≥50 MΩ (10Hz)
Input Circuit Current:	≤0.05 μA
Input Voltage Range	<±5 mVpp
Calibration Voltage:	1 mV± 2%
DC Offset Voltage	±500mV
Noise:	≤15μVp-p
Filter	Work Frequency
	DFT Filter: weak/strong
	LOWPASS Filter: 25 Hz / 35 Hz / 45 Hz / 75 Hz / 100 Hz / 150 Hz
CMRR	≥110 dB
Pacemaker Detection	
Amplitude	±2 to ±700 mV
Width	0.1 to 2.0 ms
Sampling Frequency	10,000 /sec/channel

Note: Test the accuracy of input signal reproduction according to the methods described in clause 4.2.7.2 in ANSI/AAMI EC11:1991/(R) 2001, and the result complies with clause 3.2.7.2 in ANSI/AAMI EC11:1991/(R) 2001.

Appendix 2 EMC Information

Guidance and manufacture's declaration – electromagnetic emissions- for all EQUIPMENT and SYSTEMS

<table>
<tr><th colspan="3">Guidance and manufacture's declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">SE-1010 PC ECG is intended for use in the electromagnetic environment specified below. The customer or the user of SE-1010 PC ECG should assure that it is used in such an environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>SE-1010 PC ECG uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emission
CISPR 11</td><td>Class A</td><td rowspan="3">SE-1010 PC ECG is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

Guidance and manufacture's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
SE-1010 PC ECG is intended for use in the electromagnetic environment specified below. The customer or the user of SE-1010 PC ECG should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to groud	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of SE-1010 PC ECG requires continued operation during power mains interruptions, it is recommended that SE-1010 PC ECG be powered from an uninterruptible power supply or a battery.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

<table>
<tr><th colspan="4">Guidance and manufacture's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">SE-1010 PC ECG is intended for use in the electromagnetic environment specified below. The customer or the user of SE-1010 PC ECG should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC61000-4-6</td><td>3 V_{rms}
150 kHz to 80 MHz</td><td>3V_{rms}</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of SE-1010 PC ECG, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = 1.2\sqrt{P}$
$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]
Interference may occur in the vicinity of equipment marked with the following symbol:
 </td></tr>
<tr><td>Radiated RF
IEC61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic</td></tr>
</table>

	environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which SE-1010 PC ECG is used exceeds the applicable RF compliance level above, SE-1010 PC ECG should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating SE-1010 PC ECG.
b	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and SE-1010 PC ECG			
SE-1010 PC ECG is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of SE-1010 PC ECG can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and SE-1010 PC ECG as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.38**	**0.38**	**0.73**
1	**1.2**	**1.2**	**2.3**
10	**3.8**	**3.8**	**7.3**
100	**12**	**12**	**23**
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Appendix 3 Abbreviation

Abbr	**English**
ECG	Electrocardiograph/Electrocardiogram
VCG	Vector ECG
TVCG	Time Vector ECG
QTD	QT Dispersion
FCG	Frequency ECG
HRV	Heart Rate Variability
HFECG	High Frequency ECG
HRT	Heart Rate Turbulence
SAECG	Signal Averaged ECG
TO	Turbulence Onset
TS	Turbulence Slope
VLP	Ventricular Late Potential
HR	Heart Rate
P Dur	P-wave Duration
PR Dur	P-R Interval
QRS Dur	QRS Complexes Duration
QT/QTc	Q-T Interval of the Current Lead / Normalized QT Interval
P/QRS/T	Dominant Direction of the Average Integrated ECG Vectors
Maximum/Minimum	Ratio of Maximum RR Interval to Minimum RR Interval

SDNN	Standard Deviation of Normal to Normal Intervals
RMSSD	Root Mean Square Successive Difference
LF	Low Frequency
HF	High Frequency
LF (norm)	Standard LF Power
HF (norm)	Standard HF Power
aVF	Left Foot Augmented Lead
aVL	Left Arm Augmented Lead
aVR	Right Arm Augmented Lead
LA	Left Arm
R	Right
RA	Right Arm
RL	Right Leg
ID	Identification
AC	Alternating Current
USB	Universal Serial Bus

P/N: 01.54.106666-17

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